

US3362099 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:15:34

All time stamps listed in this document are displayed in GMT

US3362099

Form: Participant Creation

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

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[Participant ID](#)

US3362099

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

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US3362099

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 10 Apr 2021 00:16:30

Generated On: 09 Jun 2021 17:15:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3362099

Folder: Screening

Form: Demographics

Data signed: (b) (4) 10 Apr 2021 00:16:30

Generated On: 09 Jun 2021 17:15:34

Date of Birth (MMM yyyy)	(b) (6) 1952
Age	68
Age Units	YEARS
Age (Derived)	68
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3362099

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 10 Apr 2021 00:16:30

Generated On: 09 Jun 2021 17:15:34

Date of Informed Consent ( <i>dd MMM yyyy</i> )	10 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3362099

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 10 Apr 2021 00:16:30

Generated On: 09 Jun 2021 17:15:34

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3362099

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 10 Apr 2021 00:16:30

Generated On: 09 Jun 2021 17:15:34

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Were any significant conditions reported?

Yes ☒

No ☐

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US3362099

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 10 Apr 2021 00:16:30

Generated On: 09 Jun 2021 17:15:34

Condition	OSTEOPORISIS
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3362099

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 10 Apr 2021 00:16:30

Generated On: 09 Jun 2021 17:15:34

Condition	POSTMENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2002
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2002
Start Year (derived)	2002
Stop Month and Year (derived)	
Stop Year (derived)	

US3362099

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 10 Apr 2021 00:16:30

Generated On: 09 Jun 2021 17:15:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	10 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	10:55 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 10:55
Height ( <i>xxx.x</i> )	166 cm
Weight ( <i>xxx.x</i> )	65.4 kg
BMI ( <i>xxx.x</i> )	23.73349 kg/m <sup>2</sup>
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)	

US3362099

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 10 Apr 2021 00:16:30

Generated On: 09 Jun 2021 17:15:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 AUG 2020

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

US3362099

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 10 Apr 2021 00:16:30

Generated On: 09 Jun 2021 17:15:34

Date of assessment (*dd MMM yyyy*) 10 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

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

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

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

Date of surgery unknown False

If Post-menopausal, date of last menstruation (*dd MMM yyyy*) UN UNK 2002

Date of last menstruation unknown False

US3362099

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Apr 2021 00:16:30

Generated On: 09 Jun 2021 17:15:34

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**Occupational Risk**

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☐ No ☒

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

**Warehouse shipping and fulfillment centers** and jobs (e.g., Amazon facilities) Yes ☐ No ☒

**Transportation and delivery services** (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

**Other** Yes ☒ No ☐

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**Specify**

REAL ESTATE AGENT

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**Location and Living Circumstances Risk (check all that apply)**

**No Risk Identified** False

**Resides in Nursing Home or Assisted Living Facility** False

US3362099

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 10 Apr 2021 00:16:30

Generated On: 09 Jun 2021 17:15:34

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

US3362099

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 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

US3362099

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

What was the date of randomization? (dd MMM yyyy) 10 AUG 2020

What was the participant's randomization number? 185104

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 ☒



US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Height	ND - Not Done
Weight	ND - Not Done

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	10:55 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 10:55
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="checkbox"/> Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	10 AUG 2020
Time of assessment (00:00-23:59)	12:41 (24 HR)
Vital Signs Date and Time (derived)	10 AUG 2020 12:41
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	69 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3362099

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

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.*

US3362099

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

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) 10 AUG 2020

What was the treatment time? (00:00-23:59) 11:58 (24 HR)

Treatment Date and Time (derived) 10 AUG 2020 11:58

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

What was the frequency of the study treatment dosing? ONCE

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

US3362099

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

10 AUG 2020

Collection time (00:00-23:59)

11:32 (24 HR)

Collection date and time (derived)

10 AUG 2020 11:32

US3362099

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Collection date (dd MMM yyyy)			10 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:30	10 AUG 2020 11:30
Nasopharyngeal Swab 2	No		

US3362099

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 12:31

PC Open Date & Time

10 AUG 2020 12:18

PC Close Date & Time

10 AUG 2020 14:48

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	10 AUG 2020 15:52
PC Open Date & Time	10 AUG 2020 15:43
PC Close Date & Time	11 AUG 2020 11:59

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:15:34

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**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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 18:54

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 14:37

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 12:07

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:15:34

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**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.

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Was **TEMPERATURE** taken?

Yes ☒

No ☐

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Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

14 AUG 2020 12:03

---

PC Open Date & Time

14 AUG 2020 12:00

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PC Close Date & Time

15 AUG 2020 11:59

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US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:15:34

**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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 AUG 2020 13:03

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 12:41

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59



US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 12:32

PC Open Date & Time

10 AUG 2020 12:18

PC Close Date & Time

10 AUG 2020 14:48

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**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

10 AUG 2020 15:53

PC Open Date & Time

10 AUG 2020 15:43

PC Close Date & Time

11 AUG 2020 11:59

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 18:54

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 AUG 2020 14:37

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 12:07

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 12:04

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 AUG 2020 13:03

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 AUG 2020 12:41

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59



US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**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 ☐

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 12:32
PC Open Date & Time	10 AUG 2020 12:18
PC Close Date & Time	10 AUG 2020 14:48

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**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 ☐

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

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

No ☒

Yes ☐

PC Time stamp	10 AUG 2020 15:53
PC Open Date & Time	10 AUG 2020 15:43
PC Close Date & Time	11 AUG 2020 11:59

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

**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 ☒

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

Yes <input type="checkbox"/>	
PC Time stamp	11 AUG 2020 18:55
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

46 of 1955

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 14:38
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59



US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**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 ☒

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 12:07
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

50 of 1955

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

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

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

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 ☒

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

Yes <input type="checkbox"/>	
PC Time stamp	15 AUG 2020 13:04
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**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 ☒

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 12:42
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59



US3362099

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3362099

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362099

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362099

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362099

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 AUG 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3362099

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362099

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	10 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	09:09 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 09:09
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG



US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	10 SEP 2020
Time of assessment (00:00-23:59)	10:30 (24 HR)
Vital Signs Date and Time (derived)	10 SEP 2020 10:30
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3362099

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

10 SEP 2020

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

US3362099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

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) 10 SEP 2020

What was the treatment time? (00:00-23:59) 09:53 (24 HR)

Treatment Date and Time (derived) 10 SEP 2020 09:53

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

US3362099

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	10 SEP 2020
Collection time (00:00-23:59)	09:30 (24 HR)
Collection date and time (derived)	10 SEP 2020 09:30

US3362099

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Collection date (dd MMM yyyy)			10 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:31	10 SEP 2020 09:31
Nasopharyngeal Swab 2	No		

US3362099

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**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

97.9 °F

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

Yes ☐  
No ☒

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

PC Time Stamp 10 SEP 2020 10:32

PC Open Date & Time 10 SEP 2020 10:13

PC Close Date & Time 10 SEP 2020 12:43

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	10 SEP 2020 15:36
PC Open Date & Time	10 SEP 2020 13:38
PC Close Date & Time	11 SEP 2020 11:59



US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 SEP 2020 12:24

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**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

97.6 °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

12 SEP 2020 12:48

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 15:45

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:15:34

**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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 SEP 2020 14:30

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:15:34

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**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 14:12

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**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):

PC Time Stamp

16 SEP 2020 16:28

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**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

10 SEP 2020 10:32

PC Open Date & Time

10 SEP 2020 10:13

PC Close Date & Time

10 SEP 2020 12:43

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**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

10 SEP 2020 15:36

PC Open Date & Time

10 SEP 2020 13:38

PC Close Date & Time

11 SEP 2020 11:59



US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 12:25

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 12:49

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 15:46

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 14:31

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

15 SEP 2020 14:13

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

16 SEP 2020 16:29

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**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 ☐

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 10:33
PC Open Date & Time	10 SEP 2020 10:13
PC Close Date & Time	10 SEP 2020 12:43



US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**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 ☐

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

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

No ☒

Yes ☐

PC Time stamp	10 SEP 2020 15:37
PC Open Date & Time	10 SEP 2020 13:38
PC Close Date & Time	11 SEP 2020 11:59

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

90 of 1955

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

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

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

92 of 1955

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 12:49
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**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 ☒

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 15:46
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59



US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

96 of 1955

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 14:31
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

98 of 1955

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 14:13
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

100 of 1955

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

Yes <input type="checkbox"/>	
PC Time stamp	16 SEP 2020 16:29
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3362099

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362099

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3362099

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362099

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362099

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

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*

US3362099

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362099

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	07 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3362099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 OCT 2020
Time of assessment (00:00-23:59)	09:10 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 09:10
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	88 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3362099

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 OCT 2020

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

US3362099

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date ( <i>dd MMM yyyy</i> )	7 OCT 2020
Collection time ( <i>00:00-23:59</i> )	09:20 (24 HR)
Collection date and time (derived)	7 OCT 2020 09:20



US3362099

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 03:31:45

Generated On: 09 Jun 2021 17:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 OCT 2020 20:59:17
Patient Cloud Open Date & Time	10 OCT 2020 00:01
Patient Cloud Close Date & Time	14 OCT 2020 23:59

US3362099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**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

17 OCT 2020 00:02:52

Patient Cloud Open Date & Time

17 OCT 2020 00:01

Patient Cloud Close Date & Time

21 OCT 2020 23:59

US3362099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**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

24 OCT 2020 05:19:49

Patient Cloud Open Date & Time

24 OCT 2020 00:01

Patient Cloud Close Date & Time

28 OCT 2020 23:59

US3362099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 NOV 2020 19:44:33
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3362099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

Patient Cloud Close Date & Time

18 NOV 2020 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**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

19 NOV 2020 13:01:46

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59



US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 04:34:33
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**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

02 DEC 2020 00:03:05

Patient Cloud Open Date & Time

02 DEC 2020 00:01

Patient Cloud Close Date & Time

06 DEC 2020 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 DEC 2020 04:45:19

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**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

16 DEC 2020 00:03:43

Patient Cloud Open Date & Time

16 DEC 2020 00:01

Patient Cloud Close Date & Time

20 DEC 2020 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 DEC 2020 08:55:08

Patient Cloud Open Date & Time

23 DEC 2020 00:01

Patient Cloud Close Date & Time

27 DEC 2020 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 DEC 2020 08:06:52

Patient Cloud Open Date & Time

30 DEC 2020 00:01

Patient Cloud Close Date & Time

03 JAN 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 16:56:26

Patient Cloud Open Date & Time

06 JAN 2021 00:01

Patient Cloud Close Date & Time

10 JAN 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 JAN 2021 05:43:05

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59



US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 JAN 2021 04:26:53
Patient Cloud Open Date & Time	20 JAN 2021 00:01
Patient Cloud Close Date & Time	24 JAN 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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 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	27 JAN 2021 12:50:35
Patient Cloud Open Date & Time	27 JAN 2021 00:01
Patient Cloud Close Date & Time	31 JAN 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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	03 FEB 2021 04:49:32
Patient Cloud Open Date & Time	03 FEB 2021 00:01
Patient Cloud Close Date & Time	07 FEB 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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	10 FEB 2021 04:41:32
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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	17 FEB 2021 02:43:15
Patient Cloud Open Date & Time	17 FEB 2021 00:01
Patient Cloud Close Date & Time	21 FEB 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**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

24 FEB 2021 03:06:50

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 03:14:05

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 07:48:54

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59



US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

<b>TIMEPOINT</b>	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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	17 MAR 2021 01:20:03
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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 <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	24 MAR 2021 10:55:19
Patient Cloud Open Date & Time	24 MAR 2021 00:01
Patient Cloud Close Date & Time	28 MAR 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**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

31 MAR 2021 11:42:06

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 APR 2021 04:21:46

Patient Cloud Open Date & Time

07 APR 2021 00:01

Patient Cloud Close Date & Time

11 APR 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 APR 2021 17:13:27

Patient Cloud Open Date & Time

14 APR 2021 00:01

Patient Cloud Close Date & Time

18 APR 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**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

21 APR 2021 03:53:32

Patient Cloud Open Date & Time

21 APR 2021 00:01

Patient Cloud Close Date & Time

25 APR 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**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

28 APR 2021 03:51:14

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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05 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2021 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**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 ☐

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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12 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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16 MAY 2021 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2021 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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26 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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30 MAY 2021 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT	DAY 299
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 JUN 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

[Patient Cloud Close Date & Time](#)

13 JUN 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

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

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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16 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUN 2021 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUN 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**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 ☐



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

[Patient Cloud Close Date & Time](#)

04 JUL 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

07 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

11 JUL 2021 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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14 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUL 2021 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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21 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 JUL 2021 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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28 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 AUG 2021 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2021 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**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 ☐

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 AUG 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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18 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 AUG 2021 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2021 23:59
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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 SEP 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 397

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

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

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

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

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

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

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

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 SEP 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 SEP 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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29 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 OCT 2021 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 OCT 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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27 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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31 OCT 2021 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2021 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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17 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 NOV 2021 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 NOV 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	01 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	05 DEC 2021 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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08 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 DEC 2021 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 DEC 2021 23:59
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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT	DAY 502
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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22 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 DEC 2021 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**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 ☐

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 JAN 2022 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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05 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 JAN 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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12 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 JAN 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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19 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 JAN 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**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 ☐

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 JAN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 JAN 2022 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

02 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 FEB 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 551

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

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

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

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

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

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

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

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



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 FEB 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 558

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

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

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

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

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

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

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

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 FEB 2022 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**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 ☐

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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02 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAR 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 MAR 2022 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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16 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAR 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

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

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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23 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAR 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

[Patient Cloud Open Date & Time](#)

30 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 APR 2022 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	06 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	10 APR 2022 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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13 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 APR 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 APR 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 APR 2022 23:59
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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT	DAY 628
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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27 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 MAY 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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04 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 MAY 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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18 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 MAY 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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25 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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29 MAY 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

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

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



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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08 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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12 JUN 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUN 2022 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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22 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 JUN 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 JUL 2022 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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06 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 JUL 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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13 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 JUL 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 712

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

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

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

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

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

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

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

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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20 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 JUL 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

27 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

31 JUL 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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03 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 AUG 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

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 ☐

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	10 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 AUG 2022 23:59
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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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17 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 AUG 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	24 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 AUG 2022 23:59
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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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31 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 SEP 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 SEP 2022 23:59

US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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14 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 SEP 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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21 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 SEP 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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[Patient Cloud Open Date & Time](#)

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28 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 OCT 2022 23:59

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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	05 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 OCT 2022 23:59
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US3362099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

US3362099

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:15:34

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		03 MAR 2021 03:14:19



US3362099

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 06 Mar 2021 04:19:27

Generated On: 09 Jun 2021 17:15:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362099

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 06 Mar 2021 04:19:26

Generated On: 09 Jun 2021 17:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362099

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362099

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362099

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362099

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362099

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3362099

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3362099

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

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

US3362099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

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) \_\_\_\_\_

US3362099

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

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.*

US3362099

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 FEB 2021
Collection time (00:00-23:59)	09:14 (24 HR)
Collection date and time (derived)	24 FEB 2021 09:14

US3362099

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362099

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3362099

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3362099

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:34

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*



**US3362099**

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

**Form: Continuing**

**Generated On: 09 Jun 2021 17:15:34**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3362099

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:15:34

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"/>

**US3362099**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 17:15:34**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---

US3362099

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

Form: Visit Date

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

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

Visit date (dd MMM yyyy)	24 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3362099

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

Form: Unblinding

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

Date of updated informed consent (dd MMM yyyy) 24 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) 24 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 \_\_\_\_\_

US3362099

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 FEB 2021
Collection time (00:00-23:59)	09:14 (24 HR)
Collection date and time (derived)	24 FEB 2021 09:14

US3362099

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 FEB 2021
Collection time (00:00 - 23:59)	09:15
Collection Date and Time (derived)	24 FEB 2021 09:15

US3362099

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 13 Mar 2021 22:12:31

Generated On: 09 Jun 2021 17:15:34

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3362099

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 00:42:59

Generated On: 09 Jun 2021 17:15:34

AEID

Adverse event

DIZZINESS

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)

03 JAN 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

03 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

320 of 1955

EAB) (1725)

US3362099

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 09 Apr 2021 00:42:59

Generated On: 09 Jun 2021 17:15:34

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

US3362099

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 00:42:59

Generated On: 09 Jun 2021 17:15:34

AEID	USA-US112-2021-MRNA-1273-P30 1000010
Adverse event	LEFT HIP FRACTURE
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)	26 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	28 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	26 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	28 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

322 of 1955

US3362099

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 00:42:59

Generated On: 09 Jun 2021 17:15:34

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

US3362099

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 09 Apr 2021 00:42:59

Generated On: 09 Jun 2021 17:15:34

---

SUBJECT REPORTED HIP  
FRACTURE ON 26JAN2021 THAT  
REQUIRED SAME DAY  
SURGICAL REPAIR AND  
HOSPITALIZATION THROUGH  
28JAN2021. AWAITING  
MEDICAL RECORDS FOR  
ADDITIONAL INFORMATION

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 14 Apr 2021 23:29:36

Generated On: 09 Jun 2021 17:15:34

---

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

Yes ☒

No ☐

---

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

---

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

Name of Medication RECLAST

Prophylaxis Yes ☐  
No ☒

Indication OSTEOPOROSIS

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

326 of 1955

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		25 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

Name of Medication CEFAZOLIN IN DEXTROSE

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP FRACTURE

Dose per administration 2/100

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

If dose unit is Other, specify G/ML

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

328 of 1955

EAB) (1725)

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	27 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	27 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

Name of Medication MORPHINE

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP FRACTURE

Dose per administration 4/1

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

If dose unit is Other, specify MG/ML

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

330 of 1955

EAB) (1725)

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

Name of Medication ONDANSETRON

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP FRACTURE

Dose per administration 4/2

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

If dose unit is Other, specify MG/ML

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)

332 of 1955

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	26 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

Name of Medication LACTATED RINGERS

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP FRACTURE

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

CONTINUOUS

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

334 of 1955

EAB) (1725)

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		28 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP FRACTURE

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

336 of 1955

EAB) (1725)

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

	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)	26 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	28 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

Name of Medication HYDROCODONE-ACETAMINOP  
HEN

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP FRACTURE

Dose per administration 7.5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

338 of 1955

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

Name of Medication HYDROMORPHONE

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP FRACTURE

Dose per administration 0.2/0.1

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify EVERY 5 MINUTES AS NEEDED

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

340 of 1955

EAB) (1725)

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

Name of Medication MELATONIN

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP FRACTURE

Dose per administration 3

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003

342 of 1955

EAB) (1725)

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

	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)	26 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 27 JAN 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

Name of Medication MORPHINE

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP FRACTURE

Dose per administration 2/0.5

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify EVERY 4 HOURS AS NEEDED

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

344 of 1955

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	28 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

Name of Medication OXYCODONE-ACETAMINOPHE  
N

Prophylaxis Yes ☐  
No ☒

Indication LEFT HIP FRACTURE

Dose per administration 7.5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

346 of 1955

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 09 Apr 2021 00:50:13

Generated On: 09 Jun 2021 17:15:34

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3362099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 00:50:14

Generated On: 09 Jun 2021 17:15:34

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3362099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 00:50:14

Generated On: 09 Jun 2021 17:15:34

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
26 JAN 2021	CANNULATED SCREW FIXATION OF LEFT FEMORAL FRACTURE	Adverse Event	

US3362099

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:15:34

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

US3362099

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:15:34

Date of study discontinuation/completion ( <i>dd MMM yyyy</i> )	
Reason for discontinuation	<div>AE (specify) <input type="checkbox"/></div> <div>SAE (specify) <input type="checkbox"/></div> <div>Complete <input type="checkbox"/></div> <div>Death <input type="checkbox"/></div> <div>Lost To Follow-up <input type="checkbox"/></div> <div>Physician decision (specify) <input type="checkbox"/></div> <div>Pregnancy <input type="checkbox"/></div> <div>Protocol deviation (specify) <input type="checkbox"/></div> <div>Study Terminated By Sponsor <input type="checkbox"/></div> <div>Withdrawal of consent by participant (specify) <input type="checkbox"/></div> <div>Other <input type="checkbox"/></div>
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	<div>Adverse event <input type="checkbox"/></div> <div>Unknown <input type="checkbox"/></div> <div>Other <input type="checkbox"/></div>
If main cause of death is Other, specify	
Date of death ( <i>dd MMM yyyy</i> )	
Was autopsy performed?	<div>Yes <input type="checkbox"/></div> <div>No <input type="checkbox"/></div> <div>Unknown <input type="checkbox"/></div>



US3362099

Folder: SAE USA-US112-2021-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

SAEID	USA-US112-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3362099

Folder: SAE USA-US112-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

SAEID	USA-US112-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/FEB/2021 15:16
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

US3362099

Folder: SAE USA-US112-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

SAEID	USA-US112-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/MAR/2021 11:20
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

US3362099

Folder: SAE USA-US112-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

SAEID	USA-US112-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/MAR/2021 12:30
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

US3362099

Folder: SAE USA-US112-2021-MRNA-1273-P301000010

Form: Safety Report Form (4)

Data signed: (b) (4) 24 Apr 2021 00:12:18

Generated On: 09 Jun 2021 17:15:34

SAEID	USA-US112-2021-MRNA-1273-P301000010
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	JORDAN
Investigator's Last Name	WHATLEY
Site Address: Street	5326 O'DONOVAN DR
Site Address: City	BATON ROUGE
Site Address: State	
Site Address: Postal Code	70808
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	02/APR/2021 20:04
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

US3362099 (Prod: Meridian Clinical Research-(Baton Rouge, Louisiana) - Platinum - PPDS)

**US3362099**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 17:15:34**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 18:32:26
User entered 'US3362099'	RWS_ENDPOINT	10 Aug 2020 15:45:33
	ENDPOINT (b) (4)	

**US3362099**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:15:34**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:51:50
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	10 Aug 2020 17:04:39



US3362099

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:15:34

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 15:45:34

US3362099

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:15:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:51:50
User entered 'Clinic (Clinic)'	Crystal Rowell (b) (4)	10 Aug 2020 17:04:39

**US3362099**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:15:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User entered 'SCRN'	System	10 Aug 2020 17:04:39

US3362099

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:34

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered (b) (6) 1952'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 15:45:35

**US3362099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:15:34**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:51:56
User entered '68'	(b) (4), (b) (6)	11 Aug 2020 14:01:32

**US3362099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:15:34**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User entered 'YEARS'	System	11 Aug 2020 14:01:32

**US3362099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:15:34**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User entered '68'	System	10 Aug 2020 17:04:57

**US3362099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:15:34**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:51:56
User entered 'Female (F)'	(b) (4), (b) (6)	11 Aug 2020 14:01:32



US3362099

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:34

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:51:56
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	11 Aug 2020 14:01:32

**US3362099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:15:34**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:51:56
User entered 'I'	(b) (4), (b) (6)	11 Aug 2020 14:01:32

US3362099

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:15:34

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:51:56
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:01:32

**US3362099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:15:34**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:51:56
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:01:32

**US3362099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:15:34**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:51:56
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:01:32

**US3362099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:15:34**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:51:56
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:01:32

**US3362099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:15:34**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:51:56
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:01:32

**US3362099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:15:34**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:51:56
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:01:32



**US3362099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:15:34**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:51:56
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:01:32

**US3362099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 17:15:34**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:51:56
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:01:32

US3362099

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:34

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:03
User entered '10 Aug 2020'	Crystal Rowell (b) (4)	10 Aug 2020 17:04:57

**US3362099**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:15:34**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User entered 'Aug 2020'	System	10 Aug 2020 17:04:57

**US3362099**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:15:34**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User entered '2020'	System	10 Aug 2020 17:04:57

**US3362099**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:15:34**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:03
User entered 'Amendment 1 (1)'	Crystal Rowell (b) (4)	10 Aug 2020 17:04:57

US3362099

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:34

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:03
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	10 Aug 2020 17:04:57

**US3362099**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:15:34**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:03
User entered empty.	Crystal Rowell (b) (4)	10 Aug 2020 17:04:57



US3362099

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:34

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:03
User entered empty.	Crystal Rowell (b) (4)	10 Aug 2020 17:04:57

**US3362099**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:15:34**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:03
User entered 'No (N)'	Crystal Rowell (b) (4)	10 Aug 2020 17:04:57

US3362099

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:15:34

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:52:03
User entered empty.	RWS_ENDPOINT	10 Aug 2020 15:45:34
	ENDPOINT (b) (4)	

**US3362099**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 17:15:34**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User entered 'I'	System	10 Aug 2020 17:05:16

US3362099

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:15:34

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:08
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	10 Aug 2020 17:05:16

US3362099

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:15:34

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:03:04

US3362099

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:15:34

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:52:29
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 13:23:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 13:23:21
Data point term sent to Coder	System	11 Aug 2020 14:04:41
User entered 'osteoporosis'	(b) (4), (b) (6)	11 Aug 2020 14:04:09

**US3362099**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:29
User entered 'un UNK 2018'	(b) (4), (b) (6)	11 Aug 2020 14:04:09



**US3362099**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:29
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:04:09

**US3362099**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:04:09

**US3362099**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:15:34**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:29
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:04:09

**US3362099**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:29
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:04:09

**US3362099**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User entered 'Jan 2018'	System	11 Aug 2020 14:04:09

**US3362099**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User entered '2018'	System	11 Aug 2020 14:04:09

**US3362099**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User entered empty.	System	11 Aug 2020 14:04:09

**US3362099**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User entered empty.	System	11 Aug 2020 14:04:09



US3362099

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:15:34

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:52:29
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:07:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Aug 2020 14:07:14
Data point term sent to Coder	System	11 Aug 2020 14:06:44
User entered 'postmenopausal'	(b) (4), (b) (6)	11 Aug 2020 14:06:03

**US3362099**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:29
User entered 'un UNK 2002'	(b) (4), (b) (6)	11 Aug 2020 14:06:03

**US3362099**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:29
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:06:03

**US3362099**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:06:03

**US3362099**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:15:34**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:29
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:06:03

**US3362099**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:29
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:06:03

**US3362099**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User entered 'Jan 2002'	System	11 Aug 2020 14:06:03

**US3362099**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User entered '2002'	System	11 Aug 2020 14:06:03



**US3362099**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User entered empty.	System	11 Aug 2020 14:06:03

**US3362099**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User entered empty.	System	11 Aug 2020 14:06:03

US3362099

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:09:45

US3362099

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:55
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:09:45

US3362099

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
User closed query 'Per CDM: Please confirm if time 10:55 is AM or PM. Thank you!' (Site from DM).	(b) (4)	25 Sep 2020 07:57:09
Query 'Per CDM: Please confirm if time 10:55 is AM or PM. Thank you!' answered with 'am' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:39:02
User opened query 'Per CDM: Please confirm if time 10:55 is AM or PM. Thank you!' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 12:33:54
DataPoint Verified.		09 Sep 2020 19:52:55
User entered '10:55'		11 Aug 2020 14:09:45

**US3362099**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User entered '10 Aug 2020 10:55'	System	11 Aug 2020 14:09:45

US3362099

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:55
User entered '166' cm	(b) (4), (b) (6)	11 Aug 2020 14:09:45
DataPoint set to visible.	System	10 Aug 2020 17:05:16

US3362099

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Sep 2020 19:52:55
User entered '65.4' kg	(b) (4), (b) (6)	11 Aug 2020 14:09:45
DataPoint set to visible.	System	10 Aug 2020 17:05:16



US3362099

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
Amendment Manager: User entered '23.73349'	System	16 Sep 2020 23:49:52
User entered '23.7'	System	11 Aug 2020 14:09:45
DataPoint set to visible.	System	10 Aug 2020 17:05:16

**US3362099**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User entered 'kg/m2'	System	11 Aug 2020 14:09:45
DataPoint set to visible.	System	10 Aug 2020 17:05:16

US3362099

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:00:10
User closed query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	25 Sep 2020 07:57:11
Query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:39:26
DataPoint Un-verified.	(b) (4), (b) (6)	24 Sep 2020 18:39:22
User entered missing code ND - Not Done; reason for change Per Query Resolution		24 Sep 2020 18:39:22
User opened query 'Per CDM: Per CCGs pages 15-16, when Screening and Visit 1 are done on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on Screening CRF. Please update accordingly.' (Site from DM).		24 Sep 2020 12:34:00
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:55
User entered '36.7' C	(b) (4), (b) (6)	11 Aug 2020 14:09:45

US3362099

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:00:10
DataPoint Un-verified.		24 Sep 2020 18:39:22
User entered empty; reason for change Data Entry Error		24 Sep 2020 18:39:22
DataPoint Verified.		09 Sep 2020 19:52:55
User entered 'Oral (Oral)'		11 Aug 2020 14:09:45

US3362099

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:52:55
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:09:45

US3362099

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:00:10
DataPoint Un-verified.		24 Sep 2020 18:39:22
User entered missing code ND - Not Done; reason for change Per Query Resolution		24 Sep 2020 18:39:22
DataPoint Verified.		09 Sep 2020 19:52:55
User entered '64'		11 Aug 2020 14:09:45

**US3362099**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User entered 'bpm'	System	11 Aug 2020 14:09:45

US3362099

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:00:10
DataPoint Un-verified.		24 Sep 2020 18:39:22
User entered missing code ND - Not Done; reason for change Per Query Resolution		24 Sep 2020 18:39:22
DataPoint Verified.		09 Sep 2020 19:52:55
User entered '17'		11 Aug 2020 14:09:45



US3362099

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User entered 'breaths/min'	System	11 Aug 2020 14:09:45

US3362099

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:00:10
DataPoint Un-verified.		24 Sep 2020 18:39:22
User entered missing code ND - Not Done; reason for change Per Query Resolution		24 Sep 2020 18:39:22
DataPoint Verified.		09 Sep 2020 19:52:55
User entered '132'		11 Aug 2020 14:09:45

**US3362099**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User entered 'mmHg'	System	11 Aug 2020 14:09:45

US3362099

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4) (u) (4), (b) (6)	10 Mar 2021 19:00:10
DataPoint Un-verified.		24 Sep 2020 18:39:22
User entered missing code ND - Not Done; reason for change Per Query Resolution		24 Sep 2020 18:39:22
DataPoint Verified.		09 Sep 2020 19:52:55
User entered '90'		11 Aug 2020 14:09:45

US3362099

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User entered 'mmHg'	System	11 Aug 2020 14:09:45

US3362099

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00

**US3362099**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00

**US3362099**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:15:34**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:10:09



US3362099

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
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 22:13:40
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	10 Sep 2020 21:56:40
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:02
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:10:09

US3362099

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:15:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:08
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:11:59

**US3362099**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:15:34**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:08
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:11:59

US3362099

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:15:34

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:08
User entered 'Post-menopausal (POST-MENOPAUSAL)'	(b) (4), (b) (6)	11 Aug 2020 14:11:59

**US3362099**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:15:34**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:08
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:11:59

US3362099

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:08
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:11:59

**US3362099**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:15:34**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:08
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:11:59

US3362099

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:08
User entered 'un UNK 2002'	(b) (4), (b) (6)	11 Aug 2020 14:11:59



**US3362099**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 09 Jun 2021 17:15:34**

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:08
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:11:59

US3362099

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:34

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4)	09 Sep 2020 19:53:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 14:14:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 14:14:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:14:48
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 14:14:10
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:14:10

US3362099

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:34

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4)	09 Sep 2020 19:53:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 14:14:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 14:14:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:14:48
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 14:14:10
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:14:10

US3362099

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:34

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:53:21
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 14:14:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 14:14:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:14:48
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 14:14:10
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:14:10

US3362099

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:34

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:53:21
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 14:14:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 14:14:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:14:48
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 14:14:10
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:14:10

US3362099

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:34

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4)	09 Sep 2020 19:53:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 14:14:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 14:14:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:14:48
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 14:14:10
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:14:10

US3362099

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:34

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:53:21
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 14:14:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 14:14:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:14:48
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 14:14:10
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:14:10

US3362099

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:34

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:53:21
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 14:14:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 14:14:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:14:48
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 14:14:10
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:14:10



US3362099

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:34

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:53:21
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 14:14:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 14:14:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:14:48
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 14:14:10
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:14:10

US3362099

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:34

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4)	09 Sep 2020 19:53:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 14:14:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 14:14:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:14:48
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 14:14:10
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:14:10

US3362099

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:34

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:53:21
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 14:14:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 14:14:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:14:48
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 14:14:10
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:14:10

US3362099

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:34

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:53:21
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 14:14:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 14:14:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Aug 2020 14:14:48
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 14:14:10
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:14:10

US3362099

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:34

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:14:10

US3362099

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:21
User entered 'real estate agent'	(b) (4), (b) (6)	11 Aug 2020 14:14:10

US3362099

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:34

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:14:10

US3362099

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:34

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:21
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:14:10



US3362099

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:34

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:21
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:14:10

US3362099

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:34

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:21
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:14:10

US3362099

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:34

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:21
User entered '0'	(b) (4), (b) (6)	11 Aug 2020 14:14:10

US3362099

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:34

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:21
User entered 'l'	(b) (4), (b) (6)	11 Aug 2020 14:14:10

US3362099

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:34

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
User entered '0'	(b) (4) (b) (4), (b) (6)	11 Aug 2020 14:14:10

US3362099

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:15:34

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 19:03:00
User signature succeeded.	Jordan Whatley (b) (4)	10 Apr 2021 00:16:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:21
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:14:10

**US3362099**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:15:34**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:34
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	10 Aug 2020 17:05:28

**US3362099**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:15:34**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:34
User entered '10 Aug 2020'	Crystal Rowell (b) (4)	10 Aug 2020 17:05:28



**US3362099**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:15:34**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:34
User entered 'Clinic (Clinic)'	Crystal Rowell (b) (4)	10 Aug 2020 17:05:28

**US3362099**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:15:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'VISIT1'	System	10 Aug 2020 17:05:28

US3362099

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4)	09 Sep 2020 19:53:41
User entered '10 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 16:39:35

US3362099

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:15:34

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:53:41
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 03:16:54
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:16:54
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	10 Aug 2020 16:39:35
User entered '185104' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	10 Aug 2020 16:39:35

US3362099

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:15:34

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4)	09 Sep 2020 19:53:41
User entered '>=65 years (3)'	(b) (4), (b) (6)	
	RWS_ENDPOINT	10 Aug 2020 16:39:35
	ENDPOINT (b) (4)	

US3362099

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:15:34

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)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:41
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:40:45

US3362099

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:15:34

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)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:41
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:40:45

**US3362099**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:15:34**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:41
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:40:45



**US3362099**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 17:15:34**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:41
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:40:45

US3362099

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:15:34

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:53:41
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 14:40:45

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:00:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 07:57:05
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:39:44
DataPoint Un-verified.	(b) (4), (b) (6)	24 Sep 2020 18:39:40
User entered missing code ND - Not Done; reason for change Per Query Resolution		24 Sep 2020 18:39:40
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).		24 Sep 2020 12:34:27
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered '166' cm	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:00:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:39:40
User entered missing code ND - Not Done; reason for change Per Query Resolution		24 Sep 2020 18:39:40
DataPoint Verified.		09 Sep 2020 19:54:23
User entered '65.4' kg		11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:00:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 07:57:05
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:39:44
DataPoint Un-verified.	(b) (4), (b) (6)	24 Sep 2020 18:39:40
User entered missing code ND - Not Done; reason for change Per Query Resolution		24 Sep 2020 18:39:40
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).		24 Sep 2020 12:34:27
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered '166' cm	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:00:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:39:40
User entered missing code ND - Not Done; reason for change Per Query Resolution		24 Sep 2020 18:39:40
DataPoint Verified.		09 Sep 2020 19:54:23
User entered '65.4' kg		11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:54:04



US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered '10:55'	(b) (4), (b) (6)	11 Aug 2020 18:54:04

**US3362099**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered '10 Aug 2020 10:55'	System	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered '36.7' C	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered '64'	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'bpm'	System	11 Aug 2020 18:54:04



US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered '17'	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'breaths/min'	System	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered '132'	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'mmHg'	System	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered '90'	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'mmHg'	System	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:34

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:00:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
User closed query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Sep 2020 07:57:05
Query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	24 Sep 2020 18:39:44
DataPoint Un-verified.	(b) (4), (b) (6)	24 Sep 2020 18:39:40
User entered missing code ND - Not Done; reason for change Per Query Resolution		24 Sep 2020 18:39:40
User opened query 'Per CDM: Per CCGs pages 15 & 16, if Screening and Day 1 were performed on the same day, Height and Weight should be recorded as 'ND' in Visit 1 Day 1. Please review and update accordingly.' (Site from DM).		24 Sep 2020 12:34:27
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered '166' cm	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:15:34

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:00:55
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 18:39:40
User entered missing code ND - Not Done; reason for change Per Query Resolution		24 Sep 2020 18:39:40
DataPoint Verified.		09 Sep 2020 19:54:23
User entered '65.4' kg		11 Aug 2020 18:54:04



US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 19:54:23
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) (6)	17 Aug 2020 09:39:30
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol, vitals taken after 30 mins. ' (Site from System).	(b) (4), (b) (6)	12 Aug 2020 14:42:15
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).		11 Aug 2020 18:54:04
User entered '12:41'	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered '10 Aug 2020 12:41'	System	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered '36.7' C	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered 'Oral (Oral)'	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 18:54:04



US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered '69'	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'bpm'	System	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered '16'	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'breaths/min'	System	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered '131'	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'mmHg'	System	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:23
User entered '83'	(b) (4), (b) (6)	11 Aug 2020 18:54:04

US3362099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'mmHg'	System	11 Aug 2020 18:54:04



US3362099

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:01:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:49:45
User entered 'No (N)' reason for change: Data Entry Error		21 Dec 2020 21:49:45
DataPoint Verified.		09 Sep 2020 19:54:30
User entered 'Yes (Y)'		11 Aug 2020 14:42:35

US3362099

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:01:05
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 21:49:45
User entered empty; reason for change Data Entry Error		21 Dec 2020 21:49:45
DataPoint Verified.		09 Sep 2020 19:54:30
User entered '10 Aug 2020'		11 Aug 2020 14:42:35

US3362099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:36
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	10 Aug 2020 17:05:50

**US3362099**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:15:34**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:36
User entered empty.	Crystal Rowell (b) (4)	10 Aug 2020 17:05:50

US3362099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:36
User entered empty.	Crystal Rowell (b) (4)	10 Aug 2020 17:05:50

US3362099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:34

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'MRNA-1273 OR PLACEBO'	System	10 Aug 2020 17:05:50

US3362099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:36
User entered '10 Aug 2020'	Crystal Rowell (b) (4)	10 Aug 2020 17:05:50

US3362099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:34

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:36
User entered '11:58'	Crystal Rowell (b) (4)	10 Aug 2020 17:05:50



US3362099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:34

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered '10 Aug 2020 11:58'	System	10 Aug 2020 17:05:50

US3362099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:36
User entered 'Left Arm (LEFT ARM)'	Crystal Rowell (b) (4)	10 Aug 2020 17:05:50

US3362099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:36
User entered 'ONCE'	System	10 Aug 2020 17:05:50

US3362099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:15:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'INTRAMUSCULAR'	System	10 Aug 2020 17:05:50

US3362099

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:50
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:43:19

US3362099

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:50
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:43:19

**US3362099**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:15:34**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:50
User entered '11:32'	(b) (4), (b) (6)	11 Aug 2020 14:43:19

**US3362099**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:15:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered '10 Aug 2020 11:32'	System	11 Aug 2020 14:43:19



US3362099

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:15:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:57
User entered '10 Aug 2020'	(b) (4), (b) (6)	11 Aug 2020 14:44:02

**US3362099**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	11 Aug 2020 14:44:02

US3362099

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:15:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:57
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:44:02

**US3362099**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:57
User entered '11:30'	(b) (4), (b) (6)	11 Aug 2020 14:44:02

**US3362099**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered '10 Aug 2020 11:30'	System	11 Aug 2020 14:44:02

US3362099

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:15:34

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	11 Aug 2020 14:44:02

US3362099

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:15:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4)	09 Sep 2020 19:54:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	11 Aug 2020 14:44:39
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Aug 2020 14:44:39
User entered 'No (N)' reason for change: Per Query Resolution	(b) (4), (b) (6)	11 Aug 2020 14:44:39
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Aug 2020 14:44:02
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:44:02

US3362099

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:15:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:54:57
User entered empty.	(b) (4), (b) (6)	11 Aug 2020 14:44:02



**US3362099**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered empty.	System	11 Aug 2020 14:44:02

US3362099

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:55:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	11 Aug 2020 14:44:45

**US3362099**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:15:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'I'	System	11 Aug 2020 14:44:45

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T12:30:57', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '33abfd25-0824-4dc5-84a4-8d3a7448f9f8'	System	10 Aug 2020 17:31:26
User entered 'Yes (Y)'	System	10 Aug 2020 17:31:26

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T12:31:07', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '33abfd25-0824-4dc5-84a4-8d3a7448f9f8'	System	10 Aug 2020 17:31:26
User entered '98.1'	System	10 Aug 2020 17:31:26

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T12:31:14', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '33abfd25-0824-4dc5-84a4-8d3a7448f9f8'	System	10 Aug 2020 17:31:26
User entered 'No (N)'	System	10 Aug 2020 17:31:26

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T12:31:25', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '33abfd25-0824-4dc5-84a4-8d3a7448f9f8'	System	10 Aug 2020 17:31:26
User entered '10 Aug 2020 12:31'	System	10 Aug 2020 17:31:26



US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '10 Aug 2020 12:18'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '10 Aug 2020 14:48'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T15:52:01', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '8a2528d9-735d-44d8-8bac-41356f28ac83'	System	10 Aug 2020 20:52:37
User entered 'Yes (Y)'	System	10 Aug 2020 20:52:37

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T15:52:24', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '8a2528d9-735d-44d8-8bac-41356f28ac83'	System	10 Aug 2020 20:52:37
User entered '97.9'	System	10 Aug 2020 20:52:37

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T15:52:28', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '8a2528d9-735d-44d8-8bac-41356f28ac83'	System	10 Aug 2020 20:52:37
User entered 'No (N)'	System	10 Aug 2020 20:52:37

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T15:52:34', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '8a2528d9-735d-44d8-8bac-41356f28ac83'	System	10 Aug 2020 20:52:37
User entered '10 Aug 2020 15:52'	System	10 Aug 2020 20:52:37

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '10 Aug 2020 15:43'	System	10 Aug 2020 17:05:50



US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 2'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-11T18:53:42', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '281e5914-c9ee-48fe-bdfc-9ac190f74092'	System	11 Aug 2020 23:54:11
User entered 'Yes (Y)'	System	11 Aug 2020 23:54:11

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-11T18:53:50', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '281e5914-c9ee-48fe-bdfc-9ac190f74092'	System	11 Aug 2020 23:54:11
User entered '98.6'	System	11 Aug 2020 23:54:11

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-11T18:53:55', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '281e5914-c9ee-48fe-bdfc-9ac190f74092'	System	11 Aug 2020 23:54:11
User entered 'No (N)'	System	11 Aug 2020 23:54:11

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-11T18:54:06', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '281e5914-c9ee-48fe-bdfc-9ac190f74092'	System	11 Aug 2020 23:54:11
User entered '11 Aug 2020 18:54'	System	11 Aug 2020 23:54:11

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 17:05:50

**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 17:05:50



US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 3'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-12T14:37:03', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'bcc509d8-0960-4169-b5a6-4045b936a735'	System	12 Aug 2020 19:37:35
User entered 'Yes (Y)'	System	12 Aug 2020 19:37:35

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-12T14:37:11', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'bcc509d8-0960-4169-b5a6-4045b936a735'	System	12 Aug 2020 19:37:35
User entered '97.3'	System	12 Aug 2020 19:37:35

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-12T14:37:15', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'bcc509d8-0960-4169-b5a6-4045b936a735'	System	12 Aug 2020 19:37:35
User entered 'No (N)'	System	12 Aug 2020 19:37:35

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-12T14:37:21', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'bcc509d8-0960-4169-b5a6-4045b936a735'	System	12 Aug 2020 19:37:35
User entered '12 Aug 2020 14:37'	System	12 Aug 2020 19:37:35

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 4'	System	10 Aug 2020 17:05:50



US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-13T12:06:37', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '61691304-8a2f-4fa5-afa5-d0b433fe1a33'	System	13 Aug 2020 17:07:01
User entered 'Yes (Y)'	System	13 Aug 2020 17:07:01

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-13T12:06:49', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '61691304-8a2f-4fa5-afa5-d0b433fe1a33'	System	13 Aug 2020 17:07:01
User entered '97.5'	System	13 Aug 2020 17:07:01

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-13T12:06:52', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '61691304-8a2f-4fa5-afa5-d0b433fe1a33'	System	13 Aug 2020 17:07:01
User entered 'No (N)'	System	13 Aug 2020 17:07:01

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-13T12:07:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '61691304-8a2f-4fa5-afa5-d0b433fe1a33'	System	13 Aug 2020 17:07:01
User entered '13 Aug 2020 12:07'	System	13 Aug 2020 17:07:01

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 5'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-14T12:03:29', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '923fdf0c-cd63-4b95-8aee-8548ef2192c9'	System	14 Aug 2020 17:04:46
User entered 'Yes (Y)'	System	14 Aug 2020 17:04:46



US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-14T12:03:37', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '923fdf0c-cd63-4b95-8aee-8548ef2192c9'	System	14 Aug 2020 17:04:46
User entered '97.7'	System	14 Aug 2020 17:04:46

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-14T12:03:41', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '923fdf0c-cd63-4b95-8aee-8548ef2192c9'	System	14 Aug 2020 17:04:46
User entered 'No (N)'	System	14 Aug 2020 17:04:46

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-14T12:03:49', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '923fdf0c-cd63-4b95-8aee-8548ef2192c9'	System	14 Aug 2020 17:04:46
User entered '14 Aug 2020 12:03'	System	14 Aug 2020 17:04:46

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 17:05:50

**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 6'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-15T13:03:24', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'e398d89d-bf03-42fb-80eb-cb6d43864d4c'	System	15 Aug 2020 18:03:42
User entered 'Yes (Y)'	System	15 Aug 2020 18:03:42

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-15T13:03:30', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'e398d89d-bf03-42fb-80eb-cb6d43864d4c'	System	15 Aug 2020 18:03:42
User entered '97.5'	System	15 Aug 2020 18:03:42



US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-15T13:03:34', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'e398d89d-bf03-42fb-80eb-cb6d43864d4c'	System	15 Aug 2020 18:03:42
User entered 'No (N)'	System	15 Aug 2020 18:03:42

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-15T13:03:39', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'e398d89d-bf03-42fb-80eb-cb6d43864d4c'	System	15 Aug 2020 18:03:42
User entered '15 Aug 2020 13:03'	System	15 Aug 2020 18:03:42

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 7'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-16T12:41:18', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '7e604ede-a865-4fb2-b420-e3371f6aad84'	System	16 Aug 2020 17:41:40
User entered 'Yes (Y)'	System	16 Aug 2020 17:41:40

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-16T12:41:25', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '7e604ede-a865-4fb2-b420-e3371f6aad84'	System	16 Aug 2020 17:41:40
User entered '97.9'	System	16 Aug 2020 17:41:40

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-16T12:41:29', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '7e604ede-a865-4fb2-b420-e3371f6aad84'	System	16 Aug 2020 17:41:40
User entered 'No (N)'	System	16 Aug 2020 17:41:40



US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-16T12:41:36', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '7e604ede-a865-4fb2-b420-e3371f6aad84'	System	16 Aug 2020 17:41:40
User entered '16 Aug 2020 12:41'	System	16 Aug 2020 17:41:40

US3362099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 17:05:50

**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T12:31:41', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd3c961a3-67b6-40ee-ae54-fc2e625a9f83'	System	10 Aug 2020 17:32:03
User entered 'None (1)'	System	10 Aug 2020 17:32:03

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T12:31:45', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd3c961a3-67b6-40ee-ae54-fc2e625a9f83'	System	10 Aug 2020 17:32:03
User entered 'No (N)'	System	10 Aug 2020 17:32:03

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T12:31:48', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd3c961a3-67b6-40ee-ae54-fc2e625a9f83'	System	10 Aug 2020 17:32:03
User entered 'No (N)'	System	10 Aug 2020 17:32:03

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T12:31:54', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd3c961a3-67b6-40ee-ae54-fc2e625a9f83'	System	10 Aug 2020 17:32:03
User entered 'None (1)'	System	10 Aug 2020 17:32:03



**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T12:32:01', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd3c961a3-67b6-40ee-ae54-fc2e625a9f83'	System	10 Aug 2020 17:32:03
User entered '10 Aug 2020 12:32'	System	10 Aug 2020 17:32:03

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '10 Aug 2020 12:18'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '10 Aug 2020 14:48'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T15:52:43', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '77d61037-03f9-4c6e-b94c-b244a82c28de'	System	10 Aug 2020 20:53:09
User entered 'None (1)'	System	10 Aug 2020 20:53:09

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T15:52:50', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '77d61037-03f9-4c6e-b94c-b244a82c28de'	System	10 Aug 2020 20:53:09
User entered 'No (N)'	System	10 Aug 2020 20:53:09

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T15:52:54', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '77d61037-03f9-4c6e-b94c-b244a82c28de'	System	10 Aug 2020 20:53:09
User entered 'No (N)'	System	10 Aug 2020 20:53:09

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T15:53:01', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '77d61037-03f9-4c6e-b94c-b244a82c28de'	System	10 Aug 2020 20:53:09
User entered 'None (1)'	System	10 Aug 2020 20:53:09



**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T15:53:07', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '77d61037-03f9-4c6e-b94c-b244a82c28de'	System	10 Aug 2020 20:53:09
User entered '10 Aug 2020 15:53'	System	10 Aug 2020 20:53:09

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '10 Aug 2020 15:43'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 2'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-11T18:54:26', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '10c753bf-a230-47d6-a052-7e2b9831ed9d'	System	11 Aug 2020 23:54:55
User entered 'None (1)'	System	11 Aug 2020 23:54:55

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-11T18:54:31', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '10c753bf-a230-47d6-a052-7e2b9831ed9d'	System	11 Aug 2020 23:54:55
User entered 'No (N)'	System	11 Aug 2020 23:54:55

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-11T18:54:37', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '10c753bf-a230-47d6-a052-7e2b9831ed9d'	System	11 Aug 2020 23:54:55
User entered 'No (N)'	System	11 Aug 2020 23:54:55

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-11T18:54:47', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '10c753bf-a230-47d6-a052-7e2b9831ed9d'	System	11 Aug 2020 23:54:55
User entered 'None (1)'	System	11 Aug 2020 23:54:55



US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-11T18:54:53', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '10c753bf-a230-47d6-a052-7e2b9831ed9d'	System	11 Aug 2020 23:54:55
User entered '11 Aug 2020 18:54'	System	11 Aug 2020 23:54:55

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 3'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-12T14:37:30', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'dcf794bd-baf1-4daf-bb42-0dd5743acd3e'	System	12 Aug 2020 19:37:51
User entered 'None (1)'	System	12 Aug 2020 19:37:51

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-12T14:37:34', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'dcf794bd-baf1-4daf-bb42-0dd5743acd3e'	System	12 Aug 2020 19:37:51
User entered 'No (N)'	System	12 Aug 2020 19:37:51

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-12T14:37:38', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'dcf794bd-baf1-4daf-bb42-0dd5743acd3e'	System	12 Aug 2020 19:37:51
User entered 'No (N)'	System	12 Aug 2020 19:37:51

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-12T14:37:41', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'dcf794bd-baf1-4daf-bb42-0dd5743acd3e'	System	12 Aug 2020 19:37:51
User entered 'None (1)'	System	12 Aug 2020 19:37:51



US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-12T14:37:45', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'dcf794bd-baf1-4daf-bb42-0dd5743acd3e'	System	12 Aug 2020 19:37:51
User entered '12 Aug 2020 14:37'	System	12 Aug 2020 19:37:51

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 4'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-13T12:07:07', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '67def12c-01f5-4387-8fe2-95ffd6090c40'	System	13 Aug 2020 17:07:29
User entered 'None (1)'	System	13 Aug 2020 17:07:29

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-13T12:07:11', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '67def12c-01f5-4387-8fe2-95ffd6090c40'	System	13 Aug 2020 17:07:29
User entered 'No (N)'	System	13 Aug 2020 17:07:29

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-13T12:07:18', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '67def12c-01f5-4387-8fe2-95ffd6090c40'	System	13 Aug 2020 17:07:29
User entered 'No (N)'	System	13 Aug 2020 17:07:29

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-13T12:07:23', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '67def12c-01f5-4387-8fe2-95ffd6090c40'	System	13 Aug 2020 17:07:29
User entered 'None (1)'	System	13 Aug 2020 17:07:29



US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-13T12:07:28', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '67def12c-01f5-4387-8fe2-95ffd6090c40'	System	13 Aug 2020 17:07:29
User entered '13 Aug 2020 12:07'	System	13 Aug 2020 17:07:29

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 17:05:50

**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 5'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-14T12:03:56', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'f9f6a3b9-a9b7-402d-b0eb-cd78584edfc6'	System	14 Aug 2020 17:04:55
User entered 'None (1)'	System	14 Aug 2020 17:04:55

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-14T12:04:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'f9f6a3b9-a9b7-402d-b0eb-cd78584edfc6'	System	14 Aug 2020 17:04:55
User entered 'No (N)'	System	14 Aug 2020 17:04:55

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-14T12:04:03', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'f9f6a3b9-a9b7-402d-b0eb-cd78584edfc6'	System	14 Aug 2020 17:04:55
User entered 'No (N)'	System	14 Aug 2020 17:04:55

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-14T12:04:07', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'f9f6a3b9-a9b7-402d-b0eb-cd78584edfc6'	System	14 Aug 2020 17:04:55
User entered 'None (1)'	System	14 Aug 2020 17:04:55



US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-14T12:04:11', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'f9f6a3b9-a9b7-402d-b0eb-cd78584edfc6'	System	14 Aug 2020 17:04:55
User entered '14 Aug 2020 12:04'	System	14 Aug 2020 17:04:55

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 17:05:50

**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 6'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-15T13:03:46', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '8e9c4ac8-abf7-4e53-a31f-b56d466be924'	System	15 Aug 2020 18:04:03
User entered 'None (1)'	System	15 Aug 2020 18:04:03

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-15T13:03:49', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '8e9c4ac8-abf7-4e53-a31f-b56d466be924'	System	15 Aug 2020 18:04:03
User entered 'No (N)'	System	15 Aug 2020 18:04:03

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-15T13:03:52', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '8e9c4ac8-abf7-4e53-a31f-b56d466be924'	System	15 Aug 2020 18:04:03
User entered 'No (N)'	System	15 Aug 2020 18:04:03

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-15T13:03:56', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '8e9c4ac8-abf7-4e53-a31f-b56d466be924'	System	15 Aug 2020 18:04:03
User entered 'None (1)'	System	15 Aug 2020 18:04:03



**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-15T13:03:59', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '8e9c4ac8-abf7-4e53-a31f-b56d466be924'	System	15 Aug 2020 18:04:03
User entered '15 Aug 2020 13:03'	System	15 Aug 2020 18:04:03

**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 7'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-16T12:41:42', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '59d12df1-e155-432f-90cf-17dd553cd099'	System	16 Aug 2020 17:41:59
User entered 'None (1)'	System	16 Aug 2020 17:41:59

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-16T12:41:45', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '59d12df1-e155-432f-90cf-17dd553cd099'	System	16 Aug 2020 17:41:59
User entered 'No (N)'	System	16 Aug 2020 17:41:59

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-16T12:41:49', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '59d12df1-e155-432f-90cf-17dd553cd099'	System	16 Aug 2020 17:41:59
User entered 'No (N)'	System	16 Aug 2020 17:41:59

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-16T12:41:52', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '59d12df1-e155-432f-90cf-17dd553cd099'	System	16 Aug 2020 17:41:59
User entered 'None (1)'	System	16 Aug 2020 17:41:59



**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-16T12:41:56', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '59d12df1-e155-432f-90cf-17dd553cd099'	System	16 Aug 2020 17:41:59
User entered '16 Aug 2020 12:41'	System	16 Aug 2020 17:41:59

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T12:32:12', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'fd83a2f6-0c9f-49cc-a6af-89fa58ac0628'	System	10 Aug 2020 17:32:40
User entered 'None (0)'	System	10 Aug 2020 17:32:40

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T12:32:16', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'fd83a2f6-0c9f-49cc-a6af-89fa58ac0628'	System	10 Aug 2020 17:32:40
User entered 'None (0)'	System	10 Aug 2020 17:32:40

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T12:32:20', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'fd83a2f6-0c9f-49cc-a6af-89fa58ac0628'	System	10 Aug 2020 17:32:40
User entered 'None (0)'	System	10 Aug 2020 17:32:40

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T12:32:23', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'fd83a2f6-0c9f-49cc-a6af-89fa58ac0628'	System	10 Aug 2020 17:32:40
User entered 'None (0)'	System	10 Aug 2020 17:32:40



US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T12:32:26', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'fd83a2f6-0c9f-49cc-a6af-89fa58ac0628'	System	10 Aug 2020 17:32:40
User entered 'None (0)'	System	10 Aug 2020 17:32:40

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T12:32:29', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'fd83a2f6-0c9f-49cc-a6af-89fa58ac0628'	System	10 Aug 2020 17:32:40
User entered 'None (0)'	System	10 Aug 2020 17:32:40

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T12:32:35', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'fd83a2f6-0c9f-49cc-a6af-89fa58ac0628'	System	10 Aug 2020 17:32:40
User entered 'No (N)'	System	10 Aug 2020 17:32:40

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T12:32:39', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'fd83a2f6-0c9f-49cc-a6af-89fa58ac0628'	System	10 Aug 2020 17:32:40
User entered '10 Aug 2020 12:32'	System	10 Aug 2020 17:32:40

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '10 Aug 2020 12:18'	System	10 Aug 2020 17:05:50

**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '10 Aug 2020 14:48'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 1, after vaccination (at home)'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T15:53:15', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'f5676ebb-4f45-43ca-96b9-8f80c447e4c8'	System	10 Aug 2020 20:53:52
User entered 'None (0)'	System	10 Aug 2020 20:53:52



US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T15:53:19', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'f5676ebb-4f45-43ca-96b9-8f80c447e4c8'	System	10 Aug 2020 20:53:52
User entered 'None (0)'	System	10 Aug 2020 20:53:52

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T15:53:23', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'f5676ebb-4f45-43ca-96b9-8f80c447e4c8'	System	10 Aug 2020 20:53:52
User entered 'None (0)'	System	10 Aug 2020 20:53:52

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T15:53:27', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'f5676ebb-4f45-43ca-96b9-8f80c447e4c8'	System	10 Aug 2020 20:53:52
User entered 'None (0)'	System	10 Aug 2020 20:53:52

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T15:53:31', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'f5676ebb-4f45-43ca-96b9-8f80c447e4c8'	System	10 Aug 2020 20:53:52
User entered 'None (0)'	System	10 Aug 2020 20:53:52

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T15:53:36', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'f5676ebb-4f45-43ca-96b9-8f80c447e4c8'	System	10 Aug 2020 20:53:52
User entered 'None (0)'	System	10 Aug 2020 20:53:52

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T15:53:39', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'f5676ebb-4f45-43ca-96b9-8f80c447e4c8'	System	10 Aug 2020 20:53:52
User entered 'No (N)'	System	10 Aug 2020 20:53:52

**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-10T15:53:50', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'f5676ebb-4f45-43ca-96b9-8f80c447e4c8'	System	10 Aug 2020 20:53:52
User entered '10 Aug 2020 15:53'	System	10 Aug 2020 20:53:52

**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '10 Aug 2020 15:43'	System	10 Aug 2020 17:05:50



US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '11 Aug 2020 11:59'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 2'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-11T18:55:01', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'cbf275f7-a08b-4961-a2fc-96ce8fa364f3'	System	11 Aug 2020 23:55:28
User entered 'None (0)'	System	11 Aug 2020 23:55:28

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-11T18:55:04', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'cbf275f7-a08b-4961-a2fc-96ce8fa364f3'	System	11 Aug 2020 23:55:28
User entered 'None (0)'	System	11 Aug 2020 23:55:28

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-11T18:55:08', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'cbf275f7-a08b-4961-a2fc-96ce8fa364f3'	System	11 Aug 2020 23:55:28
User entered 'None (0)'	System	11 Aug 2020 23:55:28

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-11T18:55:11', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'cbf275f7-a08b-4961-a2fc-96ce8fa364f3'	System	11 Aug 2020 23:55:28
User entered 'None (0)'	System	11 Aug 2020 23:55:28

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-11T18:55:14', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'cbf275f7-a08b-4961-a2fc-96ce8fa364f3'	System	11 Aug 2020 23:55:28
User entered 'None (0)'	System	11 Aug 2020 23:55:28

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-11T18:55:17', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'cbf275f7-a08b-4961-a2fc-96ce8fa364f3'	System	11 Aug 2020 23:55:28
User entered 'None (0)'	System	11 Aug 2020 23:55:28



US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-11T18:55:22', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'cbf275f7-a08b-4961-a2fc-96ce8fa364f3'	System	11 Aug 2020 23:55:28
User entered 'No (N)'	System	11 Aug 2020 23:55:28

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-11T18:55:26', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'cbf275f7-a08b-4961-a2fc-96ce8fa364f3'	System	11 Aug 2020 23:55:28
User entered '11 Aug 2020 18:55'	System	11 Aug 2020 23:55:28

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 17:05:50

**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 3'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-12T14:37:53', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'c4507e9b-03df-40ea-b880-adfa39ca2ffa'	System	12 Aug 2020 19:38:18
User entered 'None (0)'	System	12 Aug 2020 19:38:18

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-12T14:37:56', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'c4507e9b-03df-40ea-b880-adfa39ca2ffa'	System	12 Aug 2020 19:38:18
User entered 'None (0)'	System	12 Aug 2020 19:38:18

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-12T14:37:59', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'c4507e9b-03df-40ea-b880-adfa39ca2ffa'	System	12 Aug 2020 19:38:18
User entered 'None (0)'	System	12 Aug 2020 19:38:18



US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-12T14:38:02', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'c4507e9b-03df-40ea-b880-adfa39ca2ffa'	System	12 Aug 2020 19:38:18
User entered 'None (0)'	System	12 Aug 2020 19:38:18

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-12T14:38:05', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'c4507e9b-03df-40ea-b880-adfa39ca2ffa'	System	12 Aug 2020 19:38:18
User entered 'None (0)'	System	12 Aug 2020 19:38:18

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-12T14:38:07', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'c4507e9b-03df-40ea-b880-adfa39ca2ffa'	System	12 Aug 2020 19:38:18
User entered 'None (0)'	System	12 Aug 2020 19:38:18

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-12T14:38:12', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'c4507e9b-03df-40ea-b880-adfa39ca2ffa'	System	12 Aug 2020 19:38:18
User entered 'No (N)'	System	12 Aug 2020 19:38:18

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-12T14:38:15', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'c4507e9b-03df-40ea-b880-adfa39ca2ffa'	System	12 Aug 2020 19:38:18
User entered '12 Aug 2020 14:38'	System	12 Aug 2020 19:38:18

**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 4'	System	10 Aug 2020 17:05:50



US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-13T12:07:35', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'c30d654e-4d60-47fd-9064-6e248c5b4c40'	System	13 Aug 2020 17:08:01
User entered 'None (0)'	System	13 Aug 2020 17:08:01

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-13T12:07:40', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'c30d654e-4d60-47fd-9064-6e248c5b4c40'	System	13 Aug 2020 17:08:01
User entered 'None (0)'	System	13 Aug 2020 17:08:01

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-13T12:07:43', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'c30d654e-4d60-47fd-9064-6e248c5b4c40'	System	13 Aug 2020 17:08:01
User entered 'None (0)'	System	13 Aug 2020 17:08:01

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-13T12:07:47', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'c30d654e-4d60-47fd-9064-6e248c5b4c40'	System	13 Aug 2020 17:08:01
User entered 'None (0)'	System	13 Aug 2020 17:08:01

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-13T12:07:49', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'c30d654e-4d60-47fd-9064-6e248c5b4c40'	System	13 Aug 2020 17:08:01
User entered 'None (0)'	System	13 Aug 2020 17:08:01

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-13T12:07:52', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'c30d654e-4d60-47fd-9064-6e248c5b4c40'	System	13 Aug 2020 17:08:01
User entered 'None (0)'	System	13 Aug 2020 17:08:01

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-13T12:07:55', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'c30d654e-4d60-47fd-9064-6e248c5b4c40'	System	13 Aug 2020 17:08:01
User entered 'No (N)'	System	13 Aug 2020 17:08:01

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-13T12:07:58', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'c30d654e-4d60-47fd-9064-6e248c5b4c40'	System	13 Aug 2020 17:08:01
User entered '13 Aug 2020 12:07'	System	13 Aug 2020 17:08:01



US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '13 Aug 2020 12:00'	System	10 Aug 2020 17:05:50

**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '14 Aug 2020 11:59'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 5'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-14T12:04:17', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '07b31356-869a-4991-8b8e-55d7a596ffb3'	System	14 Aug 2020 17:05:12
User entered 'None (0)'	System	14 Aug 2020 17:05:12

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-14T12:04:20', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '07b31356-869a-4991-8b8e-55d7a596ffb3'	System	14 Aug 2020 17:05:12
User entered 'None (0)'	System	14 Aug 2020 17:05:12

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-14T12:04:24', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '07b31356-869a-4991-8b8e-55d7a596ffb3'	System	14 Aug 2020 17:05:12
User entered 'None (0)'	System	14 Aug 2020 17:05:12

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-14T12:04:27', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '07b31356-869a-4991-8b8e-55d7a596ffb3'	System	14 Aug 2020 17:05:12
User entered 'None (0)'	System	14 Aug 2020 17:05:12

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-14T12:04:30', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '07b31356-869a-4991-8b8e-55d7a596ffb3'	System	14 Aug 2020 17:05:12
User entered 'None (0)'	System	14 Aug 2020 17:05:12



US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-14T12:04:33', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '07b31356-869a-4991-8b8e-55d7a596ffb3'	System	14 Aug 2020 17:05:12
User entered 'None (0)'	System	14 Aug 2020 17:05:12

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-14T12:04:38', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '07b31356-869a-4991-8b8e-55d7a596ffb3'	System	14 Aug 2020 17:05:12
User entered 'No (N)'	System	14 Aug 2020 17:05:12

**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-14T12:04:41', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '07b31356-869a-4991-8b8e-55d7a596ffb3'	System	14 Aug 2020 17:05:12
User entered '14 Aug 2020 12:04'	System	14 Aug 2020 17:05:12

**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '14 Aug 2020 12:00'	System	10 Aug 2020 17:05:50

**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '15 Aug 2020 11:59'	System	10 Aug 2020 17:05:50

**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 6'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-15T13:04:04', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a5d5b73c-caaa-4c0c-bf2c-b42759ed0ca1'	System	15 Aug 2020 18:04:31
User entered 'None (0)'	System	15 Aug 2020 18:04:31

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-15T13:04:07', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a5d5b73c-caaa-4c0c-bf2c-b42759ed0ca1'	System	15 Aug 2020 18:04:31
User entered 'None (0)'	System	15 Aug 2020 18:04:31



US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-15T13:04:10', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a5d5b73c-caaa-4c0c-bf2c-b42759ed0ca1'	System	15 Aug 2020 18:04:31
User entered 'None (0)'	System	15 Aug 2020 18:04:31

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-15T13:04:13', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a5d5b73c-caaa-4c0c-bf2c-b42759ed0ca1'	System	15 Aug 2020 18:04:31
User entered 'None (0)'	System	15 Aug 2020 18:04:31

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-15T13:04:17', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a5d5b73c-caaa-4c0c-bf2c-b42759ed0ca1'	System	15 Aug 2020 18:04:31
User entered 'None (0)'	System	15 Aug 2020 18:04:31

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-15T13:04:20', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a5d5b73c-caaa-4c0c-bf2c-b42759ed0ca1'	System	15 Aug 2020 18:04:31
User entered 'None (0)'	System	15 Aug 2020 18:04:31

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-15T13:04:25', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a5d5b73c-caaa-4c0c-bf2c-b42759ed0ca1'	System	15 Aug 2020 18:04:31
User entered 'No (N)'	System	15 Aug 2020 18:04:31

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-15T13:04:28', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a5d5b73c-caaa-4c0c-bf2c-b42759ed0ca1'	System	15 Aug 2020 18:04:31
User entered '15 Aug 2020 13:04'	System	15 Aug 2020 18:04:31

**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '15 Aug 2020 12:00'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '16 Aug 2020 11:59'	System	10 Aug 2020 17:05:50



US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 7'	System	10 Aug 2020 17:05:50

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-16T12:42:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a98f3def-0cd9-42d0-92de-964b0f650bea'	System	16 Aug 2020 17:42:28
User entered 'None (0)'	System	16 Aug 2020 17:42:28

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-16T12:42:05', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a98f3def-0cd9-42d0-92de-964b0f650bea'	System	16 Aug 2020 17:42:28
User entered 'None (0)'	System	16 Aug 2020 17:42:28

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-16T12:42:08', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a98f3def-0cd9-42d0-92de-964b0f650bea'	System	16 Aug 2020 17:42:28
User entered 'None (0)'	System	16 Aug 2020 17:42:28

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-16T12:42:11', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a98f3def-0cd9-42d0-92de-964b0f650bea'	System	16 Aug 2020 17:42:28
User entered 'None (0)'	System	16 Aug 2020 17:42:28

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-16T12:42:14', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a98f3def-0cd9-42d0-92de-964b0f650bea'	System	16 Aug 2020 17:42:28
User entered 'None (0)'	System	16 Aug 2020 17:42:28

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-16T12:42:17', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a98f3def-0cd9-42d0-92de-964b0f650bea'	System	16 Aug 2020 17:42:28
User entered 'None (0)'	System	16 Aug 2020 17:42:28

US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-16T12:42:20', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a98f3def-0cd9-42d0-92de-964b0f650bea'	System	16 Aug 2020 17:42:28
User entered 'No (N)'	System	16 Aug 2020 17:42:28



US3362099

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-08-16T12:42:23', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a98f3def-0cd9-42d0-92de-964b0f650bea'	System	16 Aug 2020 17:42:28
User entered '16 Aug 2020 12:42'	System	16 Aug 2020 17:42:28

**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '16 Aug 2020 12:00'	System	10 Aug 2020 17:05:50

**US3362099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '17 Aug 2020 11:59'	System	10 Aug 2020 17:05:50

**US3362099**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:55:23
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	17 Aug 2020 20:55:57

**US3362099**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:55:23
User entered '17 Aug 2020'	Crystal Rowell (b) (4)	17 Aug 2020 20:55:57

**US3362099**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:55:23
User entered 'Contact Made (CONTACT MADE)'	Crystal Rowell (b) (4)	17 Aug 2020 20:55:57

US3362099

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:55:23
User entered empty.	Crystal Rowell (b) (4)	17 Aug 2020 20:55:57

US3362099

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:55:28
User entered 'Yes (Y)'	Crystal Rowell (b) (4)	17 Aug 2020 20:56:01



**US3362099**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:15:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'I'	System	17 Aug 2020 20:56:01

**US3362099**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:55:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 21:48:00

**US3362099**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:55:56
User entered '24 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 21:48:00

**US3362099**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:55:56
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	31 Aug 2020 21:48:00

US3362099

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:55:56
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:48:00

US3362099

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 21:48:05

**US3362099**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:15:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'I'	System	31 Aug 2020 21:48:05

**US3362099**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 21:48:34



**US3362099**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:14
User entered '31 Aug 2020'	(b) (4), (b) (6)	31 Aug 2020 21:48:34

**US3362099**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	31 Aug 2020 21:48:34

US3362099

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:14
User entered empty.	(b) (4), (b) (6)	31 Aug 2020 21:48:34

US3362099

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 19:56:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	31 Aug 2020 21:48:39

**US3362099**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:15:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'I'	System	31 Aug 2020 21:48:39

**US3362099**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:15:34**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:56:40

**US3362099**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:15:34**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:06
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 21:56:40

**US3362099**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:15:34**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:06
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	10 Sep 2020 21:56:40



**US3362099**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:15:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'VISIT2'	System	10 Sep 2020 21:56:40

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:32:57

**US3362099**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:15:34**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:32
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 15:32:57

**US3362099**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 17:15:34**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:32
User entered '09:09'	(b) (4), (b) (6)	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered '10 Sep 2020 09:09'	System	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:32
User entered '36.6' C	(b) (4), (b) (6)	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:32
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Sep 2020 15:32:57



US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:32
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:32
User entered '72'	(b) (4), (b) (6)	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'bpm'	System	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:32
User entered '18'	(b) (4), (b) (6)	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'breaths/min'	System	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:02:32
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 22:15:18
User entered '137' reason for change: Data Entry Error		21 Dec 2020 22:15:18
DataPoint Verified.		22 Sep 2020 20:45:32
User entered '132'		10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'mmHg'	System	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:32
User entered '80'	(b) (4), (b) (6)	10 Sep 2020 15:32:57



US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:15:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'mmHg'	System	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:32:57

**US3362099**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:15:34**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:32
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 15:32:57

**US3362099**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:15:34**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:32
User entered '10:30'	(b) (4), (b) (6)	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered '10 Sep 2020 10:30'	System	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:32
User entered '36.7' C	(b) (4), (b) (6)	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:32
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Sep 2020 15:32:57



**US3362099**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 17:15:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:32
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:32
User entered '60'	(b) (4), (b) (6)	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'bpm'	System	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:32
User entered '17'	(b) (4), (b) (6)	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'breaths/min'	System	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:32
User entered '131'	(b) (4), (b) (6)	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'mmHg'	System	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:32
User entered '82'	(b) (4), (b) (6)	10 Sep 2020 15:32:57



US3362099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:15:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'mmHg'	System	10 Sep 2020 15:32:57

US3362099

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:56:55

**US3362099**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:15:34**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:45:38
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 21:56:55

US3362099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:34

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:46:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 15:07:40

US3362099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:34

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:46:11
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:07:40

US3362099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:46:11
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 15:07:40

**US3362099**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 17:15:34**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'MRNA-1273 OR PLACEBO'	System	10 Sep 2020 15:07:40

US3362099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:34

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:46:11
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 15:07:40



US3362099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:34

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:46:11
User entered '09:53'	(b) (4), (b) (6)	10 Sep 2020 15:07:40

US3362099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:34

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered '10 Sep 2020 09:53'	System	10 Sep 2020 15:07:40

US3362099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:34

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:46:11
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	10 Sep 2020 15:07:40

US3362099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:34

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:46:11
User entered 'ONCE'	System	10 Sep 2020 15:07:40

US3362099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:15:34

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'INTRAMUSCULAR'	System	10 Sep 2020 15:07:40

US3362099

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:46:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:57:49

US3362099

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:46:18
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 21:57:49

**US3362099**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:15:34**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Sep 2020 20:46:18
User entered '09:30' reason for change: Data Entry Error		10 Sep 2020 21:58:59
User entered '09:09'		10 Sep 2020 21:57:49



**US3362099**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:15:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered '10 Sep 2020 09:30'	System	10 Sep 2020 21:58:59
User entered '10 Sep 2020 09:09'	System	10 Sep 2020 21:57:49

US3362099

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:15:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:46:33
User entered '10 Sep 2020'	(b) (4), (b) (6)	10 Sep 2020 21:58:31

**US3362099**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	10 Sep 2020 21:58:31

US3362099

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:15:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:46:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:58:31

**US3362099**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:46:33
User entered '09:31'	(b) (4), (b) (6)	10 Sep 2020 21:58:31

**US3362099**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered '10 Sep 2020 09:31'	System	10 Sep 2020 21:58:31

**US3362099**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	10 Sep 2020 21:58:31

US3362099

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:15:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:46:33
User entered 'No (N)'	(b) (4), (b) (6)	10 Sep 2020 21:58:31



**US3362099**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:15:34**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:46:33
User entered empty.	(b) (4), (b) (6)	10 Sep 2020 21:58:31

**US3362099**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered empty.	System	10 Sep 2020 21:58:31

US3362099

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	22 Sep 2020 20:46:40
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Sep 2020 21:59:08

**US3362099**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:15:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'I'	System	10 Sep 2020 21:59:08

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T10:31:45', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'b4cb96c8-04b9-41a1-9fa8-a910744729b8'	System	10 Sep 2020 15:32:07
User entered 'Yes (Y)'	System	10 Sep 2020 15:32:07

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T10:31:53', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'b4cb96c8-04b9-41a1-9fa8-a910744729b8'	System	10 Sep 2020 15:32:07
User entered '97.9'	System	10 Sep 2020 15:32:07

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T10:31:58', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'b4cb96c8-04b9-41a1-9fa8-a910744729b8'	System	10 Sep 2020 15:32:07
User entered 'No (N)'	System	10 Sep 2020 15:32:07



US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T10:32:04', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'b4cb96c8-04b9-41a1-9fa8-a910744729b8'	System	10 Sep 2020 15:32:07
User entered '10 Sep 2020 10:32'	System	10 Sep 2020 15:32:07

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '10 Sep 2020 10:13'	System	10 Sep 2020 15:07:40

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '10 Sep 2020 12:43'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T15:36:17', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '67568270-a194-4abb-a5bd-33ca2de3ad28'	System	10 Sep 2020 20:36:39
User entered 'Yes (Y)'	System	10 Sep 2020 20:36:39

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T15:36:26', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '67568270-a194-4abb-a5bd-33ca2de3ad28'	System	10 Sep 2020 20:36:39
User entered '98.0'	System	10 Sep 2020 20:36:39

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T15:36:30', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '67568270-a194-4abb-a5bd-33ca2de3ad28'	System	10 Sep 2020 20:36:39
User entered 'No (N)'	System	10 Sep 2020 20:36:39

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T15:36:34', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '67568270-a194-4abb-a5bd-33ca2de3ad28'	System	10 Sep 2020 20:36:39
User entered '10 Sep 2020 15:36'	System	10 Sep 2020 20:36:39



US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '10 Sep 2020 13:38'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 2'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-11T12:24:38', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'ed17546b-a1dc-452b-a7e0-af4e1b7b0d68'	System	11 Sep 2020 17:24:58
User entered 'Yes (Y)'	System	11 Sep 2020 17:24:58

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-11T12:24:43', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'ed17546b-a1dc-452b-a7e0-af4e1b7b0d68'	System	11 Sep 2020 17:24:58
User entered '97.2'	System	11 Sep 2020 17:24:58

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-11T12:24:47', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'ed17546b-a1dc-452b-a7e0-af4e1b7b0d68'	System	11 Sep 2020 17:24:58
User entered 'No (N)'	System	11 Sep 2020 17:24:58

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-11T12:24:52', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'ed17546b-a1dc-452b-a7e0-af4e1b7b0d68'	System	11 Sep 2020 17:24:58
User entered '11 Sep 2020 12:24'	System	11 Sep 2020 17:24:58

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:07:40



US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 3'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-12T12:48:26', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'e96d3b81-9567-492f-8631-0bc2a2000cbc'	System	12 Sep 2020 17:48:53
User entered 'Yes (Y)'	System	12 Sep 2020 17:48:53

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-12T12:48:37', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'e96d3b81-9567-492f-8631-0bc2a2000cbc'	System	12 Sep 2020 17:48:53
User entered '97.6'	System	12 Sep 2020 17:48:53

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-12T12:48:41', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'e96d3b81-9567-492f-8631-0bc2a2000cbc'	System	12 Sep 2020 17:48:53
User entered 'No (N)'	System	12 Sep 2020 17:48:53

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-12T12:48:50', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'e96d3b81-9567-492f-8631-0bc2a2000cbc'	System	12 Sep 2020 17:48:53
User entered '12 Sep 2020 12:48'	System	12 Sep 2020 17:48:53

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:07:40



US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 4'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-13T15:45:24', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '80346316-008f-4329-8380-d7dc143c56ac'	System	13 Sep 2020 20:46:15
User entered 'Yes (Y)'	System	13 Sep 2020 20:46:15

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-13T15:45:31', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '80346316-008f-4329-8380-d7dc143c56ac'	System	13 Sep 2020 20:46:15
User entered '98.8'	System	13 Sep 2020 20:46:15

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-13T15:45:36', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '80346316-008f-4329-8380-d7dc143c56ac'	System	13 Sep 2020 20:46:15
User entered 'No (N)'	System	13 Sep 2020 20:46:15

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-13T15:45:40', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '80346316-008f-4329-8380-d7dc143c56ac'	System	13 Sep 2020 20:46:15
User entered '13 Sep 2020 15:45'	System	13 Sep 2020 20:46:15

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 5'	System	10 Sep 2020 15:07:40



US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-14T14:30:36', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '01de2774-117a-4cbd-9599-cc81948d7d6b'	System	14 Sep 2020 19:30:55
User entered 'Yes (Y)'	System	14 Sep 2020 19:30:55

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-14T14:30:42', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '01de2774-117a-4cbd-9599-cc81948d7d6b'	System	14 Sep 2020 19:30:55
User entered '97.6'	System	14 Sep 2020 19:30:55

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-14T14:30:45', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '01de2774-117a-4cbd-9599-cc81948d7d6b'	System	14 Sep 2020 19:30:55
User entered 'No (N)'	System	14 Sep 2020 19:30:55

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-14T14:30:52', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '01de2774-117a-4cbd-9599-cc81948d7d6b'	System	14 Sep 2020 19:30:55
User entered '14 Sep 2020 14:30'	System	14 Sep 2020 19:30:55

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 6'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-15T14:12:32', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '2fef221f-f5d5-48de-b1bd-02f9ba48eaab'	System	15 Sep 2020 19:12:49
User entered 'Yes (Y)'	System	15 Sep 2020 19:12:49



US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-15T14:12:38', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '2fef221f-f5d5-48de-b1bd-02f9ba48eaab'	System	15 Sep 2020 19:12:49
User entered '97.8'	System	15 Sep 2020 19:12:49

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-15T14:12:42', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '2fef221f-f5d5-48de-b1bd-02f9ba48eaab'	System	15 Sep 2020 19:12:49
User entered 'No (N)'	System	15 Sep 2020 19:12:49

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-15T14:12:47', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '2fef221f-f5d5-48de-b1bd-02f9ba48eaab'	System	15 Sep 2020 19:12:49
User entered '15 Sep 2020 14:12'	System	15 Sep 2020 19:12:49

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:07:40

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 7'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:15:34

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-16T16:28:40', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '70e03893-80ed-44f9-a0bb-76f28c13ce8e'	System	16 Sep 2020 21:28:58
User entered 'Yes (Y)'	System	16 Sep 2020 21:28:58

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:15:34

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-16T16:28:46', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '70e03893-80ed-44f9-a0bb-76f28c13ce8e'	System	16 Sep 2020 21:28:58
User entered '97.5'	System	16 Sep 2020 21:28:58



US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-16T16:28:50', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '70e03893-80ed-44f9-a0bb-76f28c13ce8e'	System	16 Sep 2020 21:28:58
User entered 'No (N)'	System	16 Sep 2020 21:28:58

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-16T16:28:54', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '70e03893-80ed-44f9-a0bb-76f28c13ce8e'	System	16 Sep 2020 21:28:58
User entered '16 Sep 2020 16:28'	System	16 Sep 2020 21:28:58

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T10:32:25', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '5988ebff-a6c2-41d3-b31f-745b1c8bedbb'	System	10 Sep 2020 15:32:40
User entered 'None (1)'	System	10 Sep 2020 15:32:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T10:32:29', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '5988ebff-a6c2-41d3-b31f-745b1c8bedbb'	System	10 Sep 2020 15:32:40
User entered 'No (N)'	System	10 Sep 2020 15:32:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T10:32:32', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '5988ebff-a6c2-41d3-b31f-745b1c8bedbb'	System	10 Sep 2020 15:32:40
User entered 'No (N)'	System	10 Sep 2020 15:32:40



US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T10:32:35', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '5988ebff-a6c2-41d3-b31f-745b1c8bedbb'	System	10 Sep 2020 15:32:40
User entered 'None (1)'	System	10 Sep 2020 15:32:40

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T10:32:39', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '5988ebff-a6c2-41d3-b31f-745b1c8bedbb'	System	10 Sep 2020 15:32:40
User entered '10 Sep 2020 10:32'	System	10 Sep 2020 15:32:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '10 Sep 2020 10:13'	System	10 Sep 2020 15:07:40

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '10 Sep 2020 12:43'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T15:36:43', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '230180ff-4151-44ed-99e7-4f11768e73e6'	System	10 Sep 2020 20:36:58
User entered 'None (1)'	System	10 Sep 2020 20:36:58

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T15:36:47', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '230180ff-4151-44ed-99e7-4f11768e73e6'	System	10 Sep 2020 20:36:58
User entered 'No (N)'	System	10 Sep 2020 20:36:58

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T15:36:50', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '230180ff-4151-44ed-99e7-4f11768e73e6'	System	10 Sep 2020 20:36:58
User entered 'No (N)'	System	10 Sep 2020 20:36:58



US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T15:36:53', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '230180ff-4151-44ed-99e7-4f11768e73e6'	System	10 Sep 2020 20:36:58
User entered 'None (1)'	System	10 Sep 2020 20:36:58

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T15:36:56', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '230180ff-4151-44ed-99e7-4f11768e73e6'	System	10 Sep 2020 20:36:58
User entered '10 Sep 2020 15:36'	System	10 Sep 2020 20:36:58

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '10 Sep 2020 13:38'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 2'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-11T12:25:03', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '48ff0dd7-4ab0-493c-b34f-420bf92b856a'	System	11 Sep 2020 17:25:26
User entered 'None (1)'	System	11 Sep 2020 17:25:26

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-11T12:25:07', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '48ff0dd7-4ab0-493c-b34f-420bf92b856a'	System	11 Sep 2020 17:25:26
User entered 'No (N)'	System	11 Sep 2020 17:25:26

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-11T12:25:14', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '48ff0dd7-4ab0-493c-b34f-420bf92b856a'	System	11 Sep 2020 17:25:26
User entered 'No (N)'	System	11 Sep 2020 17:25:26



US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-11T12:25:20', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '48ff0dd7-4ab0-493c-b34f-420bf92b856a'	System	11 Sep 2020 17:25:26
User entered 'None (1)'	System	11 Sep 2020 17:25:26

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-11T12:25:23', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '48ff0dd7-4ab0-493c-b34f-420bf92b856a'	System	11 Sep 2020 17:25:26
User entered '11 Sep 2020 12:25'	System	11 Sep 2020 17:25:26

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 3'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-12T12:48:58', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'e3d579b3-0547-46da-ae27-40caa205157f'	System	12 Sep 2020 17:49:16
User entered 'None (1)'	System	12 Sep 2020 17:49:16

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-12T12:49:02', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'e3d579b3-0547-46da-ae27-40caa205157f'	System	12 Sep 2020 17:49:16
User entered 'No (N)'	System	12 Sep 2020 17:49:16

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-12T12:49:07', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'e3d579b3-0547-46da-ae27-40caa205157f'	System	12 Sep 2020 17:49:16
User entered 'No (N)'	System	12 Sep 2020 17:49:16



US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-12T12:49:11', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'e3d579b3-0547-46da-ae27-40caa205157f'	System	12 Sep 2020 17:49:16
User entered 'None (1)'	System	12 Sep 2020 17:49:16

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-12T12:49:14', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'e3d579b3-0547-46da-ae27-40caa205157f'	System	12 Sep 2020 17:49:16
User entered '12 Sep 2020 12:49'	System	12 Sep 2020 17:49:16

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:07:40

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 4'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-13T15:45:50', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '683b00f1-e458-4898-94af-1b200d272673'	System	13 Sep 2020 20:46:37
User entered 'None (1)'	System	13 Sep 2020 20:46:37

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-13T15:45:56', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '683b00f1-e458-4898-94af-1b200d272673'	System	13 Sep 2020 20:46:37
User entered 'No (N)'	System	13 Sep 2020 20:46:37

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-13T15:46:03', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '683b00f1-e458-4898-94af-1b200d272673'	System	13 Sep 2020 20:46:37
User entered 'No (N)'	System	13 Sep 2020 20:46:37



US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-13T15:46:08', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '683b00f1-e458-4898-94af-1b200d272673'	System	13 Sep 2020 20:46:37
User entered 'None (1)'	System	13 Sep 2020 20:46:37

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-13T15:46:11', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '683b00f1-e458-4898-94af-1b200d272673'	System	13 Sep 2020 20:46:37
User entered '13 Sep 2020 15:46'	System	13 Sep 2020 20:46:37

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 5'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-14T14:30:57', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '2b383eef-6af7-409a-b48b-682567f510cb'	System	14 Sep 2020 19:31:11
User entered 'None (1)'	System	14 Sep 2020 19:31:11

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-14T14:31:01', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '2b383eef-6af7-409a-b48b-682567f510cb'	System	14 Sep 2020 19:31:11
User entered 'No (N)'	System	14 Sep 2020 19:31:11

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-14T14:31:03', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '2b383eef-6af7-409a-b48b-682567f510cb'	System	14 Sep 2020 19:31:11
User entered 'No (N)'	System	14 Sep 2020 19:31:11



US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-14T14:31:06', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '2b383eef-6af7-409a-b48b-682567f510cb'	System	14 Sep 2020 19:31:11
User entered 'None (1)'	System	14 Sep 2020 19:31:11

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-14T14:31:10', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '2b383eef-6af7-409a-b48b-682567f510cb'	System	14 Sep 2020 19:31:11
User entered '14 Sep 2020 14:31'	System	14 Sep 2020 19:31:11

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 17:15:34

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 6'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-15T14:12:52', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'ca94ed90-3d72-4c7e-8f09-51d0c28d1f02'	System	15 Sep 2020 19:13:16
User entered 'None (1)'	System	15 Sep 2020 19:13:16

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-15T14:12:59', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'ca94ed90-3d72-4c7e-8f09-51d0c28d1f02'	System	15 Sep 2020 19:13:16
User entered 'No (N)'	System	15 Sep 2020 19:13:16

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-15T14:13:04', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'ca94ed90-3d72-4c7e-8f09-51d0c28d1f02'	System	15 Sep 2020 19:13:16
User entered 'No (N)'	System	15 Sep 2020 19:13:16



US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-15T14:13:07', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'ca94ed90-3d72-4c7e-8f09-51d0c28d1f02'	System	15 Sep 2020 19:13:16
User entered 'None (1)'	System	15 Sep 2020 19:13:16

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-15T14:13:11', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'ca94ed90-3d72-4c7e-8f09-51d0c28d1f02'	System	15 Sep 2020 19:13:16
User entered '15 Sep 2020 14:13'	System	15 Sep 2020 19:13:16

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:07:40

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 7'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-16T16:29:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd128b272-b8d6-4253-9d49-d037a8734a6b'	System	16 Sep 2020 21:29:18
User entered 'None (1)'	System	16 Sep 2020 21:29:18

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:15:34

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-16T16:29:04', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd128b272-b8d6-4253-9d49-d037a8734a6b'	System	16 Sep 2020 21:29:18
User entered 'No (N)'	System	16 Sep 2020 21:29:18

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-16T16:29:08', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd128b272-b8d6-4253-9d49-d037a8734a6b'	System	16 Sep 2020 21:29:18
User entered 'No (N)'	System	16 Sep 2020 21:29:18



US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:15:34

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-16T16:29:12', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd128b272-b8d6-4253-9d49-d037a8734a6b'	System	16 Sep 2020 21:29:18
User entered 'None (1)'	System	16 Sep 2020 21:29:18

US3362099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 17:15:34

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-16T16:29:15', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd128b272-b8d6-4253-9d49-d037a8734a6b'	System	16 Sep 2020 21:29:18
User entered '16 Sep 2020 16:29'	System	16 Sep 2020 21:29:18

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:07:40

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T10:32:47', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '6899c41a-d246-4fa4-8fb0-7d9dff956a5f'	System	10 Sep 2020 15:33:08
User entered 'None (0)'	System	10 Sep 2020 15:33:08

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T10:32:51', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '6899c41a-d246-4fa4-8fb0-7d9dff956a5f'	System	10 Sep 2020 15:33:08
User entered 'None (0)'	System	10 Sep 2020 15:33:08

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T10:32:53', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '6899c41a-d246-4fa4-8fb0-7d9dff956a5f'	System	10 Sep 2020 15:33:08
User entered 'None (0)'	System	10 Sep 2020 15:33:08



US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T10:32:56', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '6899c41a-d246-4fa4-8fb0-7d9dff956a5f'	System	10 Sep 2020 15:33:08
User entered 'None (0)'	System	10 Sep 2020 15:33:08

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T10:32:58', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '6899c41a-d246-4fa4-8fb0-7d9dff956a5f'	System	10 Sep 2020 15:33:08
User entered 'None (0)'	System	10 Sep 2020 15:33:08

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T10:33:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '6899c41a-d246-4fa4-8fb0-7d9dff956a5f'	System	10 Sep 2020 15:33:08
User entered 'None (0)'	System	10 Sep 2020 15:33:08

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T10:33:04', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '6899c41a-d246-4fa4-8fb0-7d9dff956a5f'	System	10 Sep 2020 15:33:08
User entered 'No (N)'	System	10 Sep 2020 15:33:08

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T10:33:07', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '6899c41a-d246-4fa4-8fb0-7d9dff956a5f' User entered '10 Sep 2020 10:33'	System	10 Sep 2020 15:33:08
	System	10 Sep 2020 15:33:08

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '10 Sep 2020 10:13'	System	10 Sep 2020 15:07:40

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '10 Sep 2020 12:43'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 1, after vaccination (at home)'	System	10 Sep 2020 15:07:40



US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T15:37:03', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a7c9b79e-cce5-4199-a4fe-f3972a6fc3d6'	System	10 Sep 2020 20:37:25
User entered 'None (0)'	System	10 Sep 2020 20:37:25

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T15:37:06', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a7c9b79e-cce5-4199-a4fe-f3972a6fc3d6'	System	10 Sep 2020 20:37:25
User entered 'None (0)'	System	10 Sep 2020 20:37:25

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T15:37:08', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a7c9b79e-cce5-4199-a4fe-f3972a6fc3d6'	System	10 Sep 2020 20:37:25
User entered 'None (0)'	System	10 Sep 2020 20:37:25

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T15:37:11', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a7c9b79e-cce5-4199-a4fe-f3972a6fc3d6'	System	10 Sep 2020 20:37:25
User entered 'None (0)'	System	10 Sep 2020 20:37:25

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T15:37:13', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a7c9b79e-cce5-4199-a4fe-f3972a6fc3d6'	System	10 Sep 2020 20:37:25
User entered 'None (0)'	System	10 Sep 2020 20:37:25

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T15:37:15', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a7c9b79e-cce5-4199-a4fe-f3972a6fc3d6'	System	10 Sep 2020 20:37:25
User entered 'None (0)'	System	10 Sep 2020 20:37:25

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T15:37:19', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a7c9b79e-cce5-4199-a4fe-f3972a6fc3d6'	System	10 Sep 2020 20:37:25
User entered 'No (N)'	System	10 Sep 2020 20:37:25

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-10T15:37:21', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a7c9b79e-cce5-4199-a4fe-f3972a6fc3d6'	System	10 Sep 2020 20:37:25
User entered '10 Sep 2020 15:37'	System	10 Sep 2020 20:37:25



US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '10 Sep 2020 13:38'	System	10 Sep 2020 15:07:40

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '11 Sep 2020 11:59'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 2'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-11T12:25:29', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '35b6120f-36d8-4e83-a801-5b3eed2973cd'	System	11 Sep 2020 17:26:20
User entered 'None (0)'	System	11 Sep 2020 17:26:20

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-11T12:25:32', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '35b6120f-36d8-4e83-a801-5b3eed2973cd'	System	11 Sep 2020 17:26:20
User entered 'None (0)'	System	11 Sep 2020 17:26:20

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-11T12:25:43', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '35b6120f-36d8-4e83-a801-5b3eed2973cd'	System	11 Sep 2020 17:26:20
User entered 'None (0)'	System	11 Sep 2020 17:26:20

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-11T12:25:47', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '35b6120f-36d8-4e83-a801-5b3eed2973cd'	System	11 Sep 2020 17:26:20
User entered 'None (0)'	System	11 Sep 2020 17:26:20

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:15:34**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-11T12:25:50', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '35b6120f-36d8-4e83-a801-5b3eed2973cd'	System	11 Sep 2020 17:26:20
User entered 'None (0)'	System	11 Sep 2020 17:26:20



US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-11T12:25:54', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '35b6120f-36d8-4e83-a801-5b3eed2973cd'	System	11 Sep 2020 17:26:20
User entered 'None (0)'	System	11 Sep 2020 17:26:20

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-11T12:25:59', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '35b6120f-36d8-4e83-a801-5b3eed2973cd'	System	11 Sep 2020 17:26:20
User entered 'No (N)'	System	11 Sep 2020 17:26:20

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-11T12:26:02', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '35b6120f-36d8-4e83-a801-5b3eed2973cd'	System	11 Sep 2020 17:26:20
User entered '11 Sep 2020 12:26'	System	11 Sep 2020 17:26:20

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '11 Sep 2020 12:00'	System	10 Sep 2020 15:07:40

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '12 Sep 2020 11:59'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 3'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-12T12:49:19', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd16dcd9c-6c93-4b40-bd54-cfccd7abeba5'	System	12 Sep 2020 17:49:40
User entered 'None (0)'	System	12 Sep 2020 17:49:40

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-12T12:49:22', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd16dcd9c-6c93-4b40-bd54-cfccd7abeba5'	System	12 Sep 2020 17:49:40
User entered 'None (0)'	System	12 Sep 2020 17:49:40



US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-12T12:49:25', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd16dcd9c-6c93-4b40-bd54-cfccd7abeba5'	System	12 Sep 2020 17:49:40
User entered 'None (0)'	System	12 Sep 2020 17:49:40

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-12T12:49:27', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd16dcd9c-6c93-4b40-bd54-cfccd7abeba5'	System	12 Sep 2020 17:49:40
User entered 'None (0)'	System	12 Sep 2020 17:49:40

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-12T12:49:30', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd16dcd9c-6c93-4b40-bd54-cfccd7abeba5'	System	12 Sep 2020 17:49:40
User entered 'None (0)'	System	12 Sep 2020 17:49:40

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-12T12:49:32', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd16dcd9c-6c93-4b40-bd54-cfccd7abeba5'	System	12 Sep 2020 17:49:40
User entered 'None (0)'	System	12 Sep 2020 17:49:40

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-12T12:49:35', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd16dcd9c-6c93-4b40-bd54-cfccd7abeba5'	System	12 Sep 2020 17:49:40
User entered 'No (N)'	System	12 Sep 2020 17:49:40

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-12T12:49:38', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd16dcd9c-6c93-4b40-bd54-cfccd7abeba5'	System	12 Sep 2020 17:49:40
User entered '12 Sep 2020 12:49'	System	12 Sep 2020 17:49:40

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '12 Sep 2020 12:00'	System	10 Sep 2020 15:07:40

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '13 Sep 2020 11:59'	System	10 Sep 2020 15:07:40



US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 4'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-13T15:46:20', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '883b3b5a-b14d-47f9-b1a7-f6a234b66e52'	System	13 Sep 2020 20:46:45
User entered 'None (0)'	System	13 Sep 2020 20:46:45

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-13T15:46:23', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '883b3b5a-b14d-47f9-b1a7-f6a234b66e52'	System	13 Sep 2020 20:46:45
User entered 'None (0)'	System	13 Sep 2020 20:46:45

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-13T15:46:26', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '883b3b5a-b14d-47f9-b1a7-f6a234b66e52'	System	13 Sep 2020 20:46:45
User entered 'None (0)'	System	13 Sep 2020 20:46:45

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-13T15:46:28', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '883b3b5a-b14d-47f9-b1a7-f6a234b66e52'	System	13 Sep 2020 20:46:45
User entered 'None (0)'	System	13 Sep 2020 20:46:45

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-13T15:46:31', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '883b3b5a-b14d-47f9-b1a7-f6a234b66e52'	System	13 Sep 2020 20:46:45
User entered 'None (0)'	System	13 Sep 2020 20:46:45

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-13T15:46:34', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '883b3b5a-b14d-47f9-b1a7-f6a234b66e52'	System	13 Sep 2020 20:46:45
User entered 'None (0)'	System	13 Sep 2020 20:46:45

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-13T15:46:36', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '883b3b5a-b14d-47f9-b1a7-f6a234b66e52'	System	13 Sep 2020 20:46:45
User entered 'No (N)'	System	13 Sep 2020 20:46:45



US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-13T15:46:39', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '883b3b5a-b14d-47f9-b1a7-f6a234b66e52'	System	13 Sep 2020 20:46:45
User entered '13 Sep 2020 15:46'	System	13 Sep 2020 20:46:45

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '13 Sep 2020 12:00'	System	10 Sep 2020 15:07:40

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '14 Sep 2020 11:59'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 5'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-14T14:31:15', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd2ce1254-ee3a-4cb8-8b02-2f73a14dd0e6'	System	14 Sep 2020 19:31:41
User entered 'None (0)'	System	14 Sep 2020 19:31:41

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-14T14:31:19', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd2ce1254-ee3a-4cb8-8b02-2f73a14dd0e6'	System	14 Sep 2020 19:31:41
User entered 'None (0)'	System	14 Sep 2020 19:31:41

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-14T14:31:21', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd2ce1254-ee3a-4cb8-8b02-2f73a14dd0e6'	System	14 Sep 2020 19:31:41
User entered 'None (0)'	System	14 Sep 2020 19:31:41

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-14T14:31:24', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd2ce1254-ee3a-4cb8-8b02-2f73a14dd0e6'	System	14 Sep 2020 19:31:41
User entered 'None (0)'	System	14 Sep 2020 19:31:41



US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-14T14:31:26', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd2ce1254-ee3a-4cb8-8b02-2f73a14dd0e6'	System	14 Sep 2020 19:31:41
User entered 'None (0)'	System	14 Sep 2020 19:31:41

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-14T14:31:28', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd2ce1254-ee3a-4cb8-8b02-2f73a14dd0e6'	System	14 Sep 2020 19:31:41
User entered 'None (0)'	System	14 Sep 2020 19:31:41

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-14T14:31:32', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd2ce1254-ee3a-4cb8-8b02-2f73a14dd0e6'	System	14 Sep 2020 19:31:41
User entered 'No (N)'	System	14 Sep 2020 19:31:41

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-14T14:31:35', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd2ce1254-ee3a-4cb8-8b02-2f73a14dd0e6'	System	14 Sep 2020 19:31:41
User entered '14 Sep 2020 14:31'	System	14 Sep 2020 19:31:41

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '14 Sep 2020 12:00'	System	10 Sep 2020 15:07:40

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '15 Sep 2020 11:59'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 6'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-15T14:13:29', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '1ec8d7f1-24e2-482d-a592-bdc551611d0e'	System	15 Sep 2020 19:13:59
User entered 'None (0)'	System	15 Sep 2020 19:13:59



US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-15T14:13:33', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '1ec8d7f1-24e2-482d-a592-bdc551611d0e'	System	15 Sep 2020 19:13:59
User entered 'None (0)'	System	15 Sep 2020 19:13:59

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-15T14:13:36', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '1ec8d7f1-24e2-482d-a592-bdc551611d0e'	System	15 Sep 2020 19:13:59
User entered 'None (0)'	System	15 Sep 2020 19:13:59

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-15T14:13:39', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '1ec8d7f1-24e2-482d-a592-bdc551611d0e'	System	15 Sep 2020 19:13:59
User entered 'None (0)'	System	15 Sep 2020 19:13:59

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-15T14:13:41', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '1ec8d7f1-24e2-482d-a592-bdc551611d0e'	System	15 Sep 2020 19:13:59
User entered 'None (0)'	System	15 Sep 2020 19:13:59

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-15T14:13:43', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '1ec8d7f1-24e2-482d-a592-bdc551611d0e'	System	15 Sep 2020 19:13:59
User entered 'None (0)'	System	15 Sep 2020 19:13:59

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-15T14:13:48', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '1ec8d7f1-24e2-482d-a592-bdc551611d0e'	System	15 Sep 2020 19:13:59
User entered 'No (N)'	System	15 Sep 2020 19:13:59

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-15T14:13:55', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '1ec8d7f1-24e2-482d-a592-bdc551611d0e'	System	15 Sep 2020 19:13:59
User entered '15 Sep 2020 14:13'	System	15 Sep 2020 19:13:59

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '15 Sep 2020 12:00'	System	10 Sep 2020 15:07:40



**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '16 Sep 2020 11:59'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Sep 2020 15:07:40
User entered 'Day 7'	System	10 Sep 2020 15:07:40

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-16T16:29:21', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '4ef63b19-aa40-45a8-b573-76c03ab7daf7'	System	16 Sep 2020 21:29:50
User entered 'None (0)'	System	16 Sep 2020 21:29:50

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-16T16:29:24', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '4ef63b19-aa40-45a8-b573-76c03ab7daf7'	System	16 Sep 2020 21:29:50
User entered 'None (0)'	System	16 Sep 2020 21:29:50

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-16T16:29:27', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '4ef63b19-aa40-45a8-b573-76c03ab7daf7'	System	16 Sep 2020 21:29:50
User entered 'None (0)'	System	16 Sep 2020 21:29:50

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-16T16:29:30', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '4ef63b19-aa40-45a8-b573-76c03ab7daf7'	System	16 Sep 2020 21:29:50
User entered 'None (0)'	System	16 Sep 2020 21:29:50

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-16T16:29:33', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '4ef63b19-aa40-45a8-b573-76c03ab7daf7'	System	16 Sep 2020 21:29:50
User entered 'None (0)'	System	16 Sep 2020 21:29:50

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-16T16:29:35', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '4ef63b19-aa40-45a8-b573-76c03ab7daf7'	System	16 Sep 2020 21:29:50
User entered 'None (0)'	System	16 Sep 2020 21:29:50



US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-16T16:29:41', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '4ef63b19-aa40-45a8-b573-76c03ab7daf7'	System	16 Sep 2020 21:29:50
User entered 'No (N)'	System	16 Sep 2020 21:29:50

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-09-16T16:29:44', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '4ef63b19-aa40-45a8-b573-76c03ab7daf7'	System	16 Sep 2020 21:29:50
User entered '16 Sep 2020 16:29'	System	16 Sep 2020 21:29:50

US3362099

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 17:15:34

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '16 Sep 2020 12:00'	System	10 Sep 2020 15:07:40

**US3362099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 17:15:34**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
User entered '17 Sep 2020 11:59'	System	10 Sep 2020 15:07:40

**US3362099**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:50:33
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:49:34

**US3362099**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:50:33
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 17:49:34

**US3362099**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:50:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Sep 2020 17:49:34

US3362099

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:50:33
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:49:34



US3362099

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4)	05 Oct 2020 19:50:38
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	17 Sep 2020 17:49:59
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 17:49:59
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 17:49:59
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Sep 2020 17:49:39
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:49:39

**US3362099**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:15:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'I'	System	17 Sep 2020 17:49:59
User entered empty.	System	17 Sep 2020 17:49:39

**US3362099**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:50:51
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:46:28

**US3362099**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:50:51
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 15:46:28

**US3362099**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:50:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	24 Sep 2020 15:46:28

US3362099

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:50:51
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 15:46:28

**US3362099**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:15:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	05 Oct 2020 19:50:56
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Sep 2020 15:46:33

**US3362099**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:15:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'I'	System	24 Sep 2020 15:46:33



**US3362099**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:55:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 14:52:08

**US3362099**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:55:26
User entered '01 Oct 2020'	(b) (4), (b) (6)	01 Oct 2020 14:52:08

**US3362099**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:55:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	01 Oct 2020 14:52:08

US3362099

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:55:26
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 14:52:08

US3362099

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:55:32
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 14:52:14

**US3362099**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:15:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'I'	System	01 Oct 2020 14:52:14

US3362099

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:55:49
User closed query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	07 Oct 2020 15:23:09
User opened query 'Was this visit performed is Yes, however Visit Date is missing. Please provide.' (Site from System).	System	07 Oct 2020 15:22:21
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 15:22:21

US3362099

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:34

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 15:55:49
User entered '07 Oct 2020' reason for change: Data Entry Error		07 Oct 2020 15:23:09
User entered empty.		07 Oct 2020 15:22:21



US3362099

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:55:49
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	07 Oct 2020 15:22:21

**US3362099**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:15:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'VISIT3'	System	07 Oct 2020 15:22:21

US3362099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 15:24:29

**US3362099**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:06
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 15:24:29

**US3362099**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:06
User entered '09:10'	(b) (4), (b) (6)	07 Oct 2020 15:24:29

**US3362099**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered '7 Oct 2020 09:10'	System	07 Oct 2020 15:24:29

US3362099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:06
User entered '36.8' C	(b) (4), (b) (6)	07 Oct 2020 15:24:29

**US3362099**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:06
User entered 'Oral (Oral)'	(b) (4), (b) (6)	07 Oct 2020 15:24:29



**US3362099**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:06
User entered empty.	(b) (4), (b) (6)	07 Oct 2020 15:24:29

**US3362099**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:06
User entered '88'	(b) (4), (b) (6)	07 Oct 2020 15:24:29

**US3362099**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'bpm'	System	07 Oct 2020 15:24:29

**US3362099**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:06
User entered '16'	(b) (4), (b) (6)	07 Oct 2020 15:24:29

**US3362099**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'breaths/min'	System	07 Oct 2020 15:24:29

**US3362099**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:06
User entered '139'	(b) (4), (b) (6)	07 Oct 2020 15:24:29

**US3362099**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'mmHg'	System	07 Oct 2020 15:24:29

US3362099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:06
User entered '89'	(b) (4), (b) (6)	07 Oct 2020 15:24:29



US3362099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'mmHg'	System	07 Oct 2020 15:24:29

US3362099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43

**US3362099**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43

US3362099

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:34

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 15:24:36

US3362099

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:15:34

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:17
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 15:24:36

**US3362099**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:15:34**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 15:24:57

US3362099

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:34

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:54
User entered '7 Oct 2020'	(b) (4), (b) (6)	07 Oct 2020 15:24:57

**US3362099**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:15:34**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:54
User entered '09:20'	(b) (4), (b) (6)	07 Oct 2020 15:24:57



**US3362099**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:15:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered '7 Oct 2020 09:20'	System	07 Oct 2020 15:24:57

US3362099

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	20 Feb 2021 03:31:45
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 15:56:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	07 Oct 2020 15:25:01

**US3362099**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:15:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'I'	System	07 Oct 2020 15:25:01

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 64'	System	10 Aug 2020 17:05:50

US3362099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-10-10T20:59:01', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '84e46806-d572-4b47-969b-c61357153598'	System	11 Oct 2020 00:59:22
User entered 'No (N)'	System	11 Oct 2020 00:59:22

US3362099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-10-10T20:59:07', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '84e46806-d572-4b47-969b-c61357153598'	System	11 Oct 2020 00:59:22
User entered 'No (N)'	System	11 Oct 2020 00:59:22

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-10-10T20:59:17', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '84e46806-d572-4b47-969b-c61357153598'	System	11 Oct 2020 00:59:22
User entered '10 Oct 2020 20:59:17'	System	11 Oct 2020 00:59:22

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered '10 Oct 2020 00:01'	System	10 Aug 2020 17:05:50



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered '14 Oct 2020 23:59'	System	10 Aug 2020 17:05:50

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 71'	System	10 Aug 2020 17:05:50

US3362099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-10-17T00:02:38', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '6765c5e7-1faf-41ee-8087-05653db51b74'	System	17 Oct 2020 04:02:55
User entered 'No (N)'	System	17 Oct 2020 04:02:55

US3362099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-10-17T00:02:47', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '6765c5e7-1faf-41ee-8087-05653db51b74'	System	17 Oct 2020 04:02:55
User entered 'No (N)'	System	17 Oct 2020 04:02:55

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-10-17T00:02:52', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '6765c5e7-1faf-41ee-8087-05653db51b74'	System	17 Oct 2020 04:02:55
User entered '17 Oct 2020 00:02:52'	System	17 Oct 2020 04:02:55

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered '17 Oct 2020 00:01'	System	10 Aug 2020 17:05:50

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered '21 Oct 2020 23:59'	System	10 Aug 2020 17:05:50

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 78'	System	10 Aug 2020 17:05:50



US3362099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-10-24T05:19:45', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a196e7c8-eba4-418c-9650-0ee42a85c760'	System	24 Oct 2020 10:19:52
User entered 'No (N)'	System	24 Oct 2020 10:19:52

US3362099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-10-24T05:19:38', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a196e7c8-eba4-418c-9650-0ee42a85c760'	System	24 Oct 2020 10:19:52
User entered 'No (N)'	System	24 Oct 2020 10:19:52

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-10-24T05:19:49', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'a196e7c8-eba4-418c-9650-0ee42a85c760'	System	24 Oct 2020 10:19:52
User entered '24 Oct 2020 05:19:49'	System	24 Oct 2020 10:19:52

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered '24 Oct 2020 00:01'	System	10 Aug 2020 17:05:50

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered '28 Oct 2020 23:59'	System	10 Aug 2020 17:05:50

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 92'	System	10 Aug 2020 17:05:50

US3362099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-11-07T19:44:29', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'c89f439a-8dd6-4632-929e-567394eba067'	System	08 Nov 2020 01:44:34
User entered 'No (N)'	System	08 Nov 2020 01:44:34

US3362099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:15:34

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-11-07T19:44:22', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'c89f439a-8dd6-4632-929e-567394eba067'	System	08 Nov 2020 01:44:34
User entered 'No (N)'	System	08 Nov 2020 01:44:34



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-11-07T19:44:33', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'c89f439a-8dd6-4632-929e-567394eba067'	System	08 Nov 2020 01:44:34
User entered '07 Nov 2020 19:44:33'	System	08 Nov 2020 01:44:34

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered '07 Nov 2020 00:01'	System	10 Aug 2020 17:05:50

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Feb 2021 00:25:36
Data entry locked.	System	10 Aug 2020 17:05:50
User entered '11 Nov 2020 23:59'	System	10 Aug 2020 17:05:50

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31
Data entry locked.	System	10 Aug 2020 17:05:50
User entered 'Day 99'	System	10 Aug 2020 17:05:50

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Have you been exposed to someone with 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 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31
Data entry locked.	System	10 Aug 2020 17:05:50
User entered '14 Nov 2020 00:01'	System	10 Aug 2020 17:05:50

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:10:31
Data entry locked.	System	10 Aug 2020 17:05:50
User entered '18 Nov 2020 23:59'	System	10 Aug 2020 17:05:50

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 17:10:31



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2020-11-19T13:01:33', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd0fe60e5-577c-49a9-a21c-5d3bd6a04372'	System	19 Nov 2020 19:01:55
User entered 'No (N)'	System	19 Nov 2020 19:01:55

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2020-11-19T13:01:39', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd0fe60e5-577c-49a9-a21c-5d3bd6a04372'	System	19 Nov 2020 19:01:55
User entered 'No (N)'	System	19 Nov 2020 19:01:55

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-11-19T13:01:46', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'd0fe60e5-577c-49a9-a21c-5d3bd6a04372'	System	19 Nov 2020 19:01:55
User entered '19 Nov 2020 13:01:46'	System	19 Nov 2020 19:01:55

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2020-11-25T04:34:21', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'ceb9d192-7025-41c8-9142-794534f04360'	System	25 Nov 2020 10:34:35
User entered 'No (N)'	System	25 Nov 2020 10:34:35

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2020-11-25T04:34:26', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'ceb9d192-7025-41c8-9142-794534f04360'	System	25 Nov 2020 10:34:35
User entered 'No (N)'	System	25 Nov 2020 10:34:35



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-11-25T04:34:33', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'ceb9d192-7025-41c8-9142-794534f04360'	System	25 Nov 2020 10:34:35
User entered '25 Nov 2020 04:34:33'	System	25 Nov 2020 10:34:35

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2020-12-02T00:02:55', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '5dedb3ca-ff88-44ee-8ee8-bd4f5f9fbc1d'	System	02 Dec 2020 06:03:10
User entered 'No (N)'	System	02 Dec 2020 06:03:10

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2020-12-02T00:03:01', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '5dedb3ca-ff88-44ee-8ee8-bd4f5f9fbc1d'	System	02 Dec 2020 06:03:10
User entered 'No (N)'	System	02 Dec 2020 06:03:10

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-12-02T00:03:05', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '5dedb3ca-ff88-44ee-8ee8-bd4f5f9fbc1d'	System	02 Dec 2020 06:03:10
User entered '02 Dec 2020 00:03:05'	System	02 Dec 2020 06:03:10

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 17:10:31



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2020-12-09T04:45:10', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '97d955fb-2b42-4b7e-a4d5-655971004892'	System	09 Dec 2020 10:45:22
User entered 'No (N)'	System	09 Dec 2020 10:45:22

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2020-12-09T04:45:14', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '97d955fb-2b42-4b7e-a4d5-655971004892'	System	09 Dec 2020 10:45:22
User entered 'No (N)'	System	09 Dec 2020 10:45:22

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-12-09T04:45:19', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '97d955fb-2b42-4b7e-a4d5-655971004892'	System	09 Dec 2020 10:45:22
User entered '09 Dec 2020 04:45:19'	System	09 Dec 2020 10:45:22

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 17:10:31



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2020-12-16T00:03:32', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '42227c71-7413-4cc9-93c9-8141de19f6a3'	System	16 Dec 2020 06:03:47
User entered 'No (N)'	System	16 Dec 2020 06:03:47

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2020-12-16T00:03:37', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '42227c71-7413-4cc9-93c9-8141de19f6a3'	System	16 Dec 2020 06:03:47
User entered 'No (N)'	System	16 Dec 2020 06:03:47

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-12-16T00:03:43', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '42227c71-7413-4cc9-93c9-8141de19f6a3' User entered '16 Dec 2020 00:03:43'	System	16 Dec 2020 06:03:47
	System	16 Dec 2020 06:03:47

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2020-12-23T08:55:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '091b89a3-0aa7-476c-9213-460e368ab7a8'	System	23 Dec 2020 14:55:11
User entered 'No (N)'	System	23 Dec 2020 14:55:11

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2020-12-23T08:55:04', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '091b89a3-0aa7-476c-9213-460e368ab7a8'	System	23 Dec 2020 14:55:11
User entered 'No (N)'	System	23 Dec 2020 14:55:11



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-12-23T08:55:08', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '091b89a3-0aa7-476c-9213-460e368ab7a8'	System	23 Dec 2020 14:55:11
User entered '23 Dec 2020 08:55:08'	System	23 Dec 2020 14:55:11

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2020-12-30T08:06:45', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '8d7c3bf1-2ddd-4807-9f40-e74e201b5bc9'	System	30 Dec 2020 14:07:23
User entered 'No (N)'	System	30 Dec 2020 14:07:23

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2020-12-30T08:06:48', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '8d7c3bf1-2ddd-4807-9f40-e74e201b5bc9'	System	30 Dec 2020 14:07:23
User entered 'No (N)'	System	30 Dec 2020 14:07:23

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2020-12-30T08:06:52', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '8d7c3bf1-2ddd-4807-9f40-e74e201b5bc9'	System	30 Dec 2020 14:07:23
User entered '30 Dec 2020 08:06:52'	System	30 Dec 2020 14:07:23

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 17:10:31



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2021-01-10T16:56:19', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '3be3dce4-a17d-4c12-8350-fb1f4e49044f'	System	10 Jan 2021 22:56:30
User entered 'No (N)'	System	10 Jan 2021 22:56:30

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2021-01-10T16:56:22', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '3be3dce4-a17d-4c12-8350-fb1f4e49044f'	System	10 Jan 2021 22:56:30
User entered 'No (N)'	System	10 Jan 2021 22:56:30

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2021-01-10T16:56:26', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '3be3dce4-a17d-4c12-8350-fb1f4e49044f' User entered '10 Jan 2021 16:56:26'	System	10 Jan 2021 22:56:30
	System	10 Jan 2021 22:56:30

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 17:10:31



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2021-01-13T05:42:58', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '34ec782e-8995-4e25-a447-9411deb479c0'	System	13 Jan 2021 11:43:08
User entered 'No (N)'	System	13 Jan 2021 11:43:08

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2021-01-13T05:43:01', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '34ec782e-8995-4e25-a447-9411deb479c0'	System	13 Jan 2021 11:43:08
User entered 'No (N)'	System	13 Jan 2021 11:43:08

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2021-01-13T05:43:05', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '34ec782e-8995-4e25-a447-9411deb479c0'	System	13 Jan 2021 11:43:08
User entered '13 Jan 2021 05:43:05'	System	13 Jan 2021 11:43:08

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2021-01-20T04:26:45', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '73315c4c-2fbf-4b49-88ce-245f83e8bae9'	System	20 Jan 2021 10:26:59
User entered 'No (N)'	System	20 Jan 2021 10:26:59

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2021-01-20T04:26:49', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '73315c4c-2fbf-4b49-88ce-245f83e8bae9'	System	20 Jan 2021 10:26:59
User entered 'No (N)'	System	20 Jan 2021 10:26:59



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2021-01-20T04:26:53', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '73315c4c-2fbf-4b49-88ce-245f83e8bae9' User entered '20 Jan 2021 04:26:53'	System	20 Jan 2021 10:26:59
	System	20 Jan 2021 10:26:59

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2021-01-27T12:49:59', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '9f8db7d3-f66d-4b95-b881-864d92ef2428'	System	27 Jan 2021 18:50:51
User entered 'Yes (Y)'	System	27 Jan 2021 18:50:51

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2021-01-27T12:50:03', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '9f8db7d3-f66d-4b95-b881-864d92ef2428'	System	27 Jan 2021 18:50:51
User entered 'No (N)'	System	27 Jan 2021 18:50:51

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2021-01-27T12:50:06', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '9f8db7d3-f66d-4b95-b881-864d92ef2428'	System	27 Jan 2021 18:50:51
User entered 'No (N)'	System	27 Jan 2021 18:50:51

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2021-01-27T12:50:19', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '9f8db7d3-f66d-4b95-b881-864d92ef2428'	System	27 Jan 2021 18:50:51
User entered 'Yes (Y)'	System	27 Jan 2021 18:50:51



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Please 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 (ecda81b7ca45a8c6)', Time: '2021-01-27T12:50:26', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '9f8db7d3-f66d-4b95-b881-864d92ef2428'	System	27 Jan 2021 18:50:51
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	27 Jan 2021 18:50:51

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2021-01-27T12:50:35', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '9f8db7d3-f66d-4b95-b881-864d92ef2428'	System	27 Jan 2021 18:50:51
User entered '27 Jan 2021 12:50:35'	System	27 Jan 2021 18:50:51

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2021-02-03T04:49:22', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'edd0bb52-f067-4cc7-b7d6-1fa317c2e87d'	System	03 Feb 2021 10:49:36
User entered 'No (N)'	System	03 Feb 2021 10:49:36

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2021-02-03T04:49:26', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'edd0bb52-f067-4cc7-b7d6-1fa317c2e87d'	System	03 Feb 2021 10:49:36
User entered 'No (N)'	System	03 Feb 2021 10:49:36

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2021-02-03T04:49:32', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'edd0bb52-f067-4cc7-b7d6-1fa317c2e87d' User entered '03 Feb 2021 04:49:32'	System	03 Feb 2021 10:49:36
	System	03 Feb 2021 10:49:36



**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

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

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2021-02-10T04:41:20', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'e219064d-eacb-488b-88da-45871e38ea10'	System	10 Feb 2021 10:41:35
User entered 'No (N)'	System	10 Feb 2021 10:41:35

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2021-02-10T04:41:24', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'e219064d-eacb-488b-88da-45871e38ea10'	System	10 Feb 2021 10:41:35
User entered 'No (N)'	System	10 Feb 2021 10:41:35

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2021-02-10T04:41:32', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'e219064d-eacb-488b-88da-45871e38ea10'	System	10 Feb 2021 10:41:35
User entered '10 Feb 2021 04:41:32'	System	10 Feb 2021 10:41:35

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2021-02-17T02:43:08', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'ddca74ce-1986-44c9-a566-161bfbbd79fe'	System	17 Feb 2021 08:43:18
User entered 'No (N)'	System	17 Feb 2021 08:43:18

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2021-02-17T02:43:12', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'ddca74ce-1986-44c9-a566-161bfbbd79fe'	System	17 Feb 2021 08:43:18
User entered 'No (N)'	System	17 Feb 2021 08:43:18

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2021-02-17T02:43:15', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'ddca74ce-1986-44c9-a566-161bfbbd79fe'	System	17 Feb 2021 08:43:18
User entered '17 Feb 2021 02:43:15'	System	17 Feb 2021 08:43:18

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2021-02-24T03:06:41-06:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '7ea9dc3f-5f8b-474d-bd50-2f4faaa67b5b'	System	24 Feb 2021 09:06:52
User entered 'No (N)'	System	24 Feb 2021 09:06:52



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2021-02-24T03:06:45-06:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '7ea9dc3f-5f8b-474d-bd50-2f4faaa67b5b'	System	24 Feb 2021 09:06:52
User entered 'No (N)'	System	24 Feb 2021 09:06:52

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2021-02-24T03:06:50-06:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '7ea9dc3f-5f8b-474d-bd50-2f4faaa67b5b'	System	24 Feb 2021 09:06:52
User entered '24 Feb 2021 03:06:50'	System	24 Feb 2021 09:06:52

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2021-03-03T03:13:58-06:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'ca913013-0e9d-4a9c-9e6e-b1e2a7325e36'	System	03 Mar 2021 09:14:07
User entered 'No (N)'	System	03 Mar 2021 09:14:07

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2021-03-03T03:14:02-06:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'ca913013-0e9d-4a9c-9e6e-b1e2a7325e36'	System	03 Mar 2021 09:14:07
User entered 'No (N)'	System	03 Mar 2021 09:14:07

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2021-03-03T03:14:05-06:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'ca913013-0e9d-4a9c-9e6e-b1e2a7325e36'	System	03 Mar 2021 09:14:07
User entered '03 Mar 2021 03:14:05'	System	03 Mar 2021 09:14:07



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2021-03-10T07:48:46-06:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'cc760872-a56b-4636-b543-1bdbce25f4c7'	System	10 Mar 2021 13:48:54
User entered 'No (N)'	System	10 Mar 2021 13:48:54

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2021-03-10T07:48:49-06:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'cc760872-a56b-4636-b543-1bdbce25f4c7'	System	10 Mar 2021 13:48:54
User entered 'No (N)'	System	10 Mar 2021 13:48:54

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2021-03-10T07:48:54-06:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'cc760872-a56b-4636-b543-1bdbce25f4c7'	System	10 Mar 2021 13:48:54
User entered '10 Mar 2021 07:48:54'	System	10 Mar 2021 13:48:54

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2021-03-17T01:19:54-05:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '27547279-a479-4400-b5ce-3a5f35d3f7d2'	System	17 Mar 2021 06:20:06
User entered 'No (N)'	System	17 Mar 2021 06:20:06

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2021-03-17T01:19:58-05:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '27547279-a479-4400-b5ce-3a5f35d3f7d2'	System	17 Mar 2021 06:20:06
User entered 'No (N)'	System	17 Mar 2021 06:20:06

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2021-03-17T01:20:03-05:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '27547279-a479-4400-b5ce-3a5f35d3f7d2'	System	17 Mar 2021 06:20:06
User entered '17 Mar 2021 01:20:03'	System	17 Mar 2021 06:20:06

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2021-03-24T10:55:06-05:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'f6f83e7f-0392-440f-aacd-4e57c517960a' User entered 'No (N)'	System	24 Mar 2021 15:55:24
	System	24 Mar 2021 15:55:24



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2021-03-24T10:55:09-05:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'f6f83e7f-0392-440f-aacd-4e57c517960a' User entered 'No (N)'	System	24 Mar 2021 15:55:24
	System	24 Mar 2021 15:55:24

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2021-03-24T10:55:19-05:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'f6f83e7f-0392-440f-aacd-4e57c517960a' User entered '24 Mar 2021 10:55:19'	System	24 Mar 2021 15:55:24
	System	24 Mar 2021 15:55:24

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2021-03-31T11:41:58-05:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '5ae83978-a615-4ad7-a31d-47e5560e1db2'	System	31 Mar 2021 16:42:12
User entered 'No (N)'	System	31 Mar 2021 16:42:12

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2021-03-31T11:42:02-05:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '5ae83978-a615-4ad7-a31d-47e5560e1db2'	System	31 Mar 2021 16:42:12
User entered 'No (N)'	System	31 Mar 2021 16:42:12

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2021-03-31T11:42:06-05:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '5ae83978-a615-4ad7-a31d-47e5560e1db2' User entered '31 Mar 2021 11:42:06'	System	31 Mar 2021 16:42:12
	System	31 Mar 2021 16:42:12



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2021-04-07T04:21:38-05:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '7b09fbdb-1f82-463e-8c93-195d7e92c392'	System	07 Apr 2021 09:21:48
User entered 'No (N)'	System	07 Apr 2021 09:21:48

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2021-04-07T04:21:42-05:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '7b09fbdb-1f82-463e-8c93-195d7e92c392'	System	07 Apr 2021 09:21:48
User entered 'No (N)'	System	07 Apr 2021 09:21:48

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2021-04-07T04:21:46-05:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '7b09fbdb-1f82-463e-8c93-195d7e92c392'	System	07 Apr 2021 09:21:48
User entered '07 Apr 2021 04:21:46'	System	07 Apr 2021 09:21:48

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2021-04-14T17:13:21-05:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'e64d08df-0fe8-488e-96e6-2b2ed2359c6d'	System	14 Apr 2021 22:14:23
User entered 'No (N)'	System	14 Apr 2021 22:14:23

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2021-04-14T17:13:24-05:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'e64d08df-0fe8-488e-96e6-2b2ed2359c6d'	System	14 Apr 2021 22:14:23
User entered 'No (N)'	System	14 Apr 2021 22:14:23

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2021-04-14T17:13:27-05:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'e64d08df-0fe8-488e-96e6-2b2ed2359c6d'	System	14 Apr 2021 22:14:23
User entered '14 Apr 2021 17:13:27'	System	14 Apr 2021 22:14:23

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2021-04-21T03:53:23-05:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '10b5c339-d6a1-42dc-8ba3-c88410951340'	System	21 Apr 2021 08:53:39
User entered 'No (N)'	System	21 Apr 2021 08:53:39



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2021-04-21T03:53:27-05:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '10b5c339-d6a1-42dc-8ba3-c88410951340'	System	21 Apr 2021 08:53:39
User entered 'No (N)'	System	21 Apr 2021 08:53:39

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2021-04-21T03:53:32-05:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '10b5c339-d6a1-42dc-8ba3-c88410951340'	System	21 Apr 2021 08:53:39
User entered '21 Apr 2021 03:53:32'	System	21 Apr 2021 08:53:39

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[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 (ecda81b7ca45a8c6)', Time: '2021-04-28T03:51:07-05:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'b868b8b6-4c80-4c59-a8aa-09b966097655'	System	29 Apr 2021 01:45:30
User entered 'No (N)'	System	29 Apr 2021 01:45:30

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Have you been exposed to someone with 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 (ecda81b7ca45a8c6)', Time: '2021-04-28T03:51:10-05:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'b868b8b6-4c80-4c59-a8aa-09b966097655'	System	29 Apr 2021 01:45:30
User entered 'No (N)'	System	29 Apr 2021 01:45:30

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2021-04-28T03:51:14-05:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: 'b868b8b6-4c80-4c59-a8aa-09b966097655'	System	29 Apr 2021 01:45:30
User entered '28 Apr 2021 03:51:14'	System	29 Apr 2021 01:45:30



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 17:10:31



**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 17:10:31

**US3362099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 17:15:34**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:10:31
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 17:10:31

US3362099

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:15:34**

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 10:42:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2021-03-03T03:14:13-06:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '93f0e7b1-dbd2-4e66-90b9-2ebdb7a6364d' User entered 'No (N)'	System	03 Mar 2021 09:14:19
	System	03 Mar 2021 09:14:19

**US3362099**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 10:42:01
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (ecda81b7ca45a8c6)', Time: '2021-03-03T03:14:19-06:00', User OID: 'PatientReportedOutcome (US3362099)', ODM File OID: '93f0e7b1-dbd2-4e66-90b9-2ebdb7a6364d' User entered '03 Mar 2021 03:14:19'	System	03 Mar 2021 09:14:19
	System	03 Mar 2021 09:14:19



**US3362099**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:19:28
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:13:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 15:09:17

**US3362099**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:19:28
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:13:14
User entered '02 Nov 2020'	(b) (4), (b) (6)	02 Nov 2020 15:09:17

**US3362099**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:19:28
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:13:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	02 Nov 2020 15:09:17

US3362099

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:19:28
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:13:14
User entered empty.	(b) (4), (b) (6)	02 Nov 2020 15:09:17

US3362099

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User signature succeeded.	Jordan Whatley (b) (4)	06 Mar 2021 04:19:28
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 22:13:19
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Nov 2020 15:09:22

**US3362099**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:15:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 19:16:43
User entered 'I'	System	02 Nov 2020 15:09:22

**US3362099**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:22:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:04:53
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	08 Dec 2020 15:58:26

**US3362099**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:22:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:04:53
User entered '8 Dec 2020'	Alexandra Caillouet (b) (4)	08 Dec 2020 15:58:26



**US3362099**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:22:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:04:53
User entered 'Contact Made (CONTACT MADE)'	Alexandra Caillouet (b) (4)	08 Dec 2020 15:58:26

US3362099

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:22:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:04:53
User entered empty.	Alexandra Caillouet (b) (4)	08 Dec 2020 15:58:26

US3362099

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:22:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:04:58
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	08 Dec 2020 15:58:31

**US3362099**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:15:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:22:38
User entered 'I'	System	08 Dec 2020 15:58:31

**US3362099**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:22:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:57:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 19:27:06

**US3362099**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:22:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:57:06
User entered '05 Jan 2021'	(b) (4), (b) (6)	05 Jan 2021 19:27:06

**US3362099**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:22:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:57:06
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Jan 2021 19:27:06

US3362099

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:22:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:57:06
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 19:27:06



**US3362099**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:15:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:22:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:58:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 19:27:09

**US3362099**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:15:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:22:38
User entered 'I'	System	05 Jan 2021 19:27:09

**US3362099**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:22:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:05:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:07:15

**US3362099**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:22:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:05:59
User entered '4 Feb 2021'	(b) (4), (b) (6)	04 Feb 2021 21:07:15

**US3362099**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:22:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:05:59
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	04 Feb 2021 21:07:15

US3362099

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:15:34

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:22:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:05:59
User entered empty.	(b) (4), (b) (6)	04 Feb 2021 21:07:15

**US3362099**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:15:34**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:22:38
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 18:15:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Feb 2021 21:07:27

**US3362099**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:15:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 02:22:38
User entered 'I'	System	04 Feb 2021 21:07:27



US3362099

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
User closed query 'Per CDM: Vital signs info missing. Please complete this section of the eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Mar 2021 18:43:48
Query 'Per CDM: Vital signs info missing. Please complete this section of the eCRF. ' answered with 'updated' (Site from DM).	Crystal Rowell (b) (4) (b) (4)	29 Mar 2021 21:40:50
User opened query 'Per CDM: Vital signs info missing. Please complete this section of the eCRF. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 19:55:15
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:06:26
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	26 Feb 2021 14:23:50

**US3362099**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:15:34**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:06:26
User entered '24 Feb 2021'	Alexandra Caillouet (b) (4)	26 Feb 2021 14:23:50

US3362099

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:34

[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 08:34:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:06:26
User entered 'Clinic (Clinic)'	Alexandra Caillouet (b) (4)	26 Feb 2021 14:23:50

**US3362099**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:15:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User entered 'VISIT4'	System	26 Feb 2021 14:23:50

**US3362099**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:06
User entered 'No (N)'	Crystal Rowell (b) (4)	29 Mar 2021 21:41:21

**US3362099**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:06
User entered empty.	Crystal Rowell (b) (4)	29 Mar 2021 21:41:21

**US3362099**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:06
User entered empty.	Crystal Rowell (b) (4)	29 Mar 2021 21:41:21

**US3362099**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User entered empty.	System	29 Mar 2021 21:41:21



US3362099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:06
User entered empty.	Crystal Rowell (b) (4)	29 Mar 2021 21:41:21

**US3362099**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:06
User entered empty.	Crystal Rowell (b) (4)	29 Mar 2021 21:41:21

**US3362099**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:06
User entered empty.	Crystal Rowell (b) (4)	29 Mar 2021 21:41:21

**US3362099**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:06
User entered empty.	Crystal Rowell (b) (4)	29 Mar 2021 21:41:21

**US3362099**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User entered empty.	System	29 Mar 2021 21:41:21

US3362099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:06
User entered empty.	Crystal Rowell (b) (4)	29 Mar 2021 21:41:21

**US3362099**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User entered empty.	System	29 Mar 2021 21:41:21

US3362099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:06
User entered empty.	Crystal Rowell (b) (4)	29 Mar 2021 21:41:21



**US3362099**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User entered empty.	System	29 Mar 2021 21:41:21

**US3362099**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:06
User entered empty.	Crystal Rowell (b) (4)	29 Mar 2021 21:41:21

**US3362099**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User entered empty.	System	29 Mar 2021 21:41:21

**US3362099**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 17:15:34**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24

US3362099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:15:34

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24

**US3362099**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:15:34**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:06:32
User entered 'No (N)'	Alexandra Caillouet (b) (4)	26 Feb 2021 14:24:29

**US3362099**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 17:15:34**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:06:32
User entered empty.	Alexandra Caillouet (b) (4)	26 Feb 2021 14:24:29

US3362099

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:26
User closed query 'Per CDM: Please be aware that Visit 4 and OL-D1 took place exactly the same day. However, "Immunogenicity Assessment" is recorded here as NO but in OL-D1 it is captured. Please clarify why there is a difference or update the field. Thank you! ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 19:55:33
User entered 'Yes (Y)' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	26 Mar 2021 13:57:11
Query 'Per CDM: Please be aware that Visit 4 and OL-D1 took place exactly the same day. However, "Immunogenicity Assessment" is recorded here as NO but in OL-D1 it is captured. Please clarify why there is a difference or update the field. Thank you! ' answered with 'This was a combined visit. Physical was required and completed for OL-D1. Per protocol, physical was symptom directed and not required for visit 4, and that is why it was marked as not completed in source and EDC. ' (Site from DM).	Alexandra Caillouet (b) (4)	26 Mar 2021 13:54:31
User opened query 'Per CDM: Please be aware that Visit 4 and OL-D1 took place exactly the same day. However, "Immunogenicity Assessment" is recorded here as NO but in OL-D1 it is captured. Please clarify why there is a difference or update the field. Thank you! ' (Site from DM).	(b) (4), (b) (6)	25 Mar 2021 23:01:27
User entered 'No (N)'	Amy Thomassie (b) (4)	19 Mar 2021 20:27:41



US3362099

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:16:26
User entered '24 Feb 2021' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	26 Mar 2021 13:57:11
User entered empty.	Amy Thomassie (b) (4)	19 Mar 2021 20:27:41

**US3362099**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:15:34**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Apr 2021 16:16:26
User entered '09:14' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	26 Mar 2021 13:57:11
User entered empty.	Amy Thomassie (b) (4) (b) (4)	19 Mar 2021 20:27:41

**US3362099**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:15:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User entered '24 Feb 2021 09:14'	System	26 Mar 2021 13:57:11
User entered empty.	System	19 Mar 2021 20:27:41

US3362099

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:05
User entered 'Yes (Y)'	Alexandra Caillouet (b) (4)	26 Feb 2021 14:25:06

**US3362099**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:15:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 08:34:24
User entered 'I'	System	26 Feb 2021 14:25:06

**US3362099**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:17:09
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 17:07:35

**US3362099**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:17:09
User entered '5 Apr 2021'	(b) (4), (b) (6)	05 Apr 2021 17:07:35

**US3362099**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:17:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Apr 2021 17:07:35



**US3362099**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 17:15:34**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:17:09
User entered empty.	(b) (4), (b) (6)	05 Apr 2021 17:07:35

US3362099

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:15:34

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Apr 2021 16:17:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Apr 2021 17:07:28

**US3362099**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 17:15:34**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Apr 2021 17:07:28

US3362099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:34

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:28
User entered 'Yes (Y)'	Alexandra Caillouet	26 Feb 2021 14:25:35
	(b) (4)	

US3362099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:34

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:28
User entered '24 Feb 2021'	Alexandra Caillouet	26 Feb 2021 14:25:35
	(b) (4)	

US3362099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:15:34

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:28
User entered 'Clinic (Clinic)'	Alexandra Caillouet	26 Feb 2021 14:25:35
	(b) (4)	

**US3362099**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 17:15:34**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User entered 'UNBLND_DECIDE'	System	26 Feb 2021 14:25:35

US3362099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:15:34

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:35
User entered '24 Feb 2021'	Alexandra Caillouet	26 Feb 2021 14:26:06
	(b) (4)	



**US3362099**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:15:34**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:04:19

US3362099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:15:34

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:35
User entered 'Yes (Y)'	Alexandra Caillouet	26 Feb 2021 14:26:06
	(b) (4)	

US3362099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:15:34

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 12:04:19

US3362099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:15:34

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:35
User entered '24 Feb 2021'	Alexandra Caillouet	26 Feb 2021 14:26:06
	(b) (4)	

US3362099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:15:34

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:35
User entered 'mRNA-1273 (mRNA-1273)'	Alexandra Caillouet	26 Feb 2021 14:26:06
	(b) (4)	

US3362099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:15:34

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:35
User entered 'mRNA-1273 (mRNA-1273)'	Alexandra Caillouet	26 Feb 2021 14:26:06
	(b) (4)	

US3362099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:15:34

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:35
User entered 'mRNA-1273 (mRNA-1273)'	Alexandra Caillouet	26 Feb 2021 14:26:06
	(b) (4)	

US3362099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:15:34

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:35
User entered 'No (N)'	Alexandra Caillouet	26 Feb 2021 14:26:06
	(b) (4)	



**US3362099**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:15:34**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User entered empty.	System	26 Feb 2021 14:26:06

**US3362099**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 09 Jun 2021 17:15:34**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User entered empty.	System	26 Feb 2021 14:26:06

US3362099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:51
User entered 'Yes (Y)'	Alexandra Caillouet	26 Feb 2021 14:26:51
	(b) (4)	

US3362099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:51
User entered '24 Feb 2021'	Alexandra Caillouet	26 Feb 2021 14:26:51
	(b) (4)	

US3362099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:15:34

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:51
User entered '09:14'	Alexandra Caillouet	26 Feb 2021 14:26:51
	(b) (4)	

**US3362099**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 17:15:34**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User entered '24 Feb 2021 09:14'	System	26 Feb 2021 14:26:51

US3362099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:15:34

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:57
User entered 'Yes (Y)'	Alexandra Caillouet	26 Feb 2021 14:27:04
	(b) (4)	

US3362099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:15:34

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:57
User entered '24 Feb 2021'	Alexandra Caillouet	26 Feb 2021 14:27:04
	(b) (4)	



US3362099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:15:34

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:07:57
User entered '09:15'	Alexandra Caillouet	26 Feb 2021 14:27:04
	(b) (4)	

**US3362099**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 17:15:34**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:59:37
User entered '24 Feb 2021 09:15'	System	26 Feb 2021 14:27:04

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 17:15:34**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:16
User signature succeeded.	Jordan Whatley (b) (4)	13 Mar 2021 22:12:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:08:27
User entered 'Yes (Y)' reason for change: New Information		05 Jan 2021 21:15:54
User entered 'No (N)'		26 Aug 2020 16:56:39

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31

US3362099

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:34

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:09:05
User coded data point as SOC: Nervous system disorders, HLT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Jan 2021 21:21:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	05 Jan 2021 21:21:37
Data point term sent to Coder	System	05 Jan 2021 21:20:25
User entered 'DIZZINESS'	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered 'No (N)'	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered 'No (N)'	(b) (4), (b) (6)	05 Jan 2021 21:19:45



**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered '03 Jan 2021'	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User entered empty.	System	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered 'No (N)'	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered '03 Jan 2021'	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User entered empty.	System	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4), (b) (6)	05 Jan 2021 21:19:45



US3362099

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:34

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered 'No (N)'	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered '0'	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered '0'	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered '0'	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

**Hospital Admission Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 21:19:45



**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered '0'	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered '0'	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered '0'	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	05 Jan 2021 21:19:45

US3362099

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:34

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	10 Mar 2021 19:09:05
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Jan 2021 21:19:58
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	05 Jan 2021 21:19:45
User entered '0'	(b) (4), (b) (6)	05 Jan 2021 21:19:45

US3362099

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:15:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered '1' reason for change: Per Query Resolution		05 Jan 2021 21:19:58
User entered '0'		05 Jan 2021 21:19:45



**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered '0'	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered empty.	(b) (4), (b) (6)	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User entered '0'	System	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31
User entered 'I'	System	05 Jan 2021 21:19:45

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 16:39:31

US3362099

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:34

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:15:48
User entered		
'USA-US112-2021-mRNA-1273-P301000010'	System	22 Feb 2021 20:15:38
User entered 'New'	(b) (4), (b) (6)	22 Feb 2021 20:15:38



US3362099

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:34

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:18:09
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hip fracture, LLT: Hip fracture - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 16:50:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Mar 2021 16:50:33
Data point term sent to Coder	System	19 Mar 2021 16:49:32
DataPoint Un-verified.	Alexandra Caillouet	19 Mar 2021 16:48:46
Coding entries removed.	(b) (4)	19 Mar 2021 16:48:46
User entered 'LEFT HIP FRACTURE' reason for change: Data Entry Error	Alexandra Caillouet	19 Mar 2021 16:48:46
DataPoint Verified.	(b) (4)	10 Mar 2021 19:09:05
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Hip fracture, LLT: Hip fracture - version MedDRA\\23.0.	Coder Import (b) (4)	19 Feb 2021 22:14:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Feb 2021 22:14:00
Data point term sent to Coder	System	19 Feb 2021 22:13:34
User entered 'hip fracture'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered 'No (N)'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

US3362099

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:34

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered 'No (N)'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered '26 Jan 2021'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered empty.	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 22:12:55

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered 'No (N)'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	



**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered '28 Jan 2021'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered empty.	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 22:12:55

US3362099

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:34

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered 'Grade 4 (Grade 4)'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered 'Yes (Y)'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered '0'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

US3362099

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:34

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered '0'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered 'I'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	



US3362099

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:34

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered '26 Jan 2021'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

US3362099

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:34

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered '28 Jan 2021'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered 'No (N)'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered empty.	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered '0'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered '0'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

US3362099

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:34

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered '0'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

US3362099

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:34

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered 'Not Related (NOT RELATED)'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	



**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered 'Not Related (NOT RELATED)'	Amy Thomassie (b) (4) (b) (4)	19 Feb 2021 22:12:55

US3362099

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:34

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 22:14:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 22:14:04
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Amy Thomassie (b) (4)	19 Feb 2021 22:14:04
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 22:12:55
User entered empty.	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered '0'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

US3362099

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:34

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 15:19:53
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'will update' (Site from Safety).	Alexandra Caillouet (b) (4)	18 Mar 2021 20:49:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 15:04:16
User entered 'I'	Amy Thomassie (b) (4) (b) (4)	19 Feb 2021 22:12:55

US3362099

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:34

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:18:09
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:42:59
User closed query 'Per DM CLR: Please review if Action taken should also include Concomitant Procedure as Con Proc recorded that matches this AE within this timeframe. Please review and update action taken as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:37:37
Query 'Per DM CLR: Please review if Action taken should also include Concomitant Procedure as Con Proc recorded that matches this AE within this timeframe. Please review and update action taken as appropriate. ' answered with 'updated' (Site from DM).	Alexandra Caillouet (b) (4)	01 Apr 2021 19:32:36
DataPoint Un-verified.	Alexandra Caillouet (b) (4)	01 Apr 2021 19:32:14
Signature has been broken.	Alexandra Caillouet (b) (4)	01 Apr 2021 19:32:14
User entered '1' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	01 Apr 2021 19:32:14
User opened query 'Per DM CLR: Please review if Action taken should also include Concomitant Procedure as Con Proc recorded that matches this AE within this timeframe. Please review and update action taken as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 14:32:39
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered '0'	Amy Thomassie (b) (4) (b) (4)	19 Feb 2021 22:12:55

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User entered empty.	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55
	(b) (4)	

US3362099

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:34

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	23 Mar 2021 00:51:12
User closed query 'Per DM CLR: SAE Narrative = Surgical Repair. However, there is no record of this procedure in concomitant procedure. Please review and ensure to update all appropriate ecrf fields. Else, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 19:25:36
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 15:20:07
User closed query 'PV Query: Please provide details of how hip fracture occurred.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 15:20:04
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'No COVID-19 testing or results found in hospital admission records.' (Site from Safety).	Alexandra Caillouet (b) (4)	18 Mar 2021 21:39:04
Query 'Per DM CLR: SAE Narrative = Surgical Repair. However, there is no record of this procedure in concomitant procedure. Please review and ensure to update all appropriate ecrf fields. Else, clarify. ' answered with 'Con procedure updated. ' (Site from DM).	Alexandra Caillouet (b) (4)	18 Mar 2021 20:45:40
Query 'PV Query: Please provide details of how hip fracture occurred.' answered with 'Subject tripped and fell resulting in the fracture.' (Site from Safety).	Alexandra Caillouet (b) (4)	18 Mar 2021 20:39:24
DataPoint Verified.	(b) (4), (b) (6)	10 Mar 2021 19:09:05
User opened query 'Per DM CLR: SAE Narrative = Surgical Repair. However, there is no record of this procedure in concomitant procedure. Please review and ensure to update all appropriate ecrf fields. Else, clarify. ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 13:29:46



US3362099

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:15:34

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 15:04:34
User opened query 'PV Query: Please provide details of how hip fracture occurred.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 15:04:26
User entered 'Subject reported hip fracture on 26JAN2021 that required same day surgical repair and hospitalization through 28Jan2021. Awaiting medical records for additional information'	Amy Thomassie (b) (4)	19 Feb 2021 22:12:55

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 22:12:55

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 22:12:55

**US3362099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Feb 2021 22:12:55

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:15:34

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:16
User signature succeeded.	Jordan Whatley (b) (4)	14 Apr 2021 23:29:36
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:18:53
User closed query 'Per ETRTR: According to SAE page "Hip Fracture", medication was provided for SAE. Please confirm and add Medication dosing details in this folder for "Hip Fracture", thanks.' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 16:18:49
Query 'Per ETRTR: According to SAE page "Hip Fracture", medication was provided for SAE. Please confirm and add Medication dosing details in this folder for "Hip Fracture", thanks.' answered with 'All medicines were added with indication left hip fracture and SAE was corrected with laterality to include left hip fracture.' (Site from CRA).	Alexandra Caillouet (b) (4)	19 Mar 2021 16:49:29
User opened query 'Per ETRTR: According to SAE page "Hip Fracture", medication was provided for SAE. Please confirm and add Medication dosing details in this folder for "Hip Fracture", thanks.' (Site from CRA).	(b) (4), (b) (6)	04 Mar 2021 20:54:11
User entered 'Yes (Y)' reason for change: New Information	Amy Thomassie (b) (4)	19 Feb 2021 22:14:33
User entered 'No (N)' reason for change: New Information	Amy Thomassie (b) (4)	19 Feb 2021 22:05:10
User entered 'Yes (Y)' reason for change: New Information	(b) (4), (b) (6)	05 Jan 2021 21:15:37
User closed query 'Per DMR-Were any prior/concomitant medications and/or vaccinations taken? Is given as 'Yes', however, no medication has been recorded in the 'Prior/Concomitant Medication and Vaccination' form. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	18 Sep 2020 05:38:19
Query 'Per DMR-Were any prior/concomitant medications and/or vaccinations taken? Is given as 'Yes', however, no medication has been recorded in the 'Prior/Concomitant Medication and Vaccination' form. Kindly review and update else clarify.' answered with 'query updated.' (Site from DM).	(b) (4), (b) (6)	17 Sep 2020 15:17:17

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:15:34

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Sep 2020 15:17:06
User opened query 'Per DMR-Were any prior/concomitant medications and/or vaccinations taken? Is given as 'Yes', however, no medication has been recorded in the 'Prior/Concomitant Medication and Vaccination' form. Kindly review and update else clarify.' (Site from DM).	(b) (4), (b) (6)	15 Sep 2020 09:40:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Crystal Rowell (b) (4)	11 Aug 2020 19:37:05
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 15:03:04

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:10:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: ZOLEDRONIC ACID, PRODUCTSYNONYM: RECLAST - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 22:17:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 22:17:58
Data point term sent to Coder User entered 'REclast'	System	19 Feb 2021 22:17:39
	Amy Thomassie (b) (4)	19 Feb 2021 22:17:10
	(b) (4)	
DataPoint activated with code reason code Data required.	Amy Thomassie (b) (4)	19 Feb 2021 22:14:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 21:20:19

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:34

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:10:51
User entered 'No (N)'	Amy Thomassie (b) (4)	19 Feb 2021 22:17:10
	(b) (4)	
DataPoint activated with code reason code Data required.	Amy Thomassie (b) (4)	19 Feb 2021 22:14:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 21:20:19



US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:34

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:10:51
User entered 'osteoporosis'	Amy Thomassie (b) (4)	19 Feb 2021 22:17:10
	(b) (4)	
DataPoint activated with code reason code Data required.	Amy Thomassie (b) (4)	19 Feb 2021 22:14:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 21:20:19

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:34

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:10:51
User entered '5'	Amy Thomassie (b) (4)	19 Feb 2021 22:17:10
	(b) (4)	
DataPoint activated with code reason code Data required.	Amy Thomassie (b) (4)	19 Feb 2021 22:14:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 21:20:19

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:34

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:10:51
User entered 'mg (mg)'	Amy Thomassie (b) (4)	19 Feb 2021 22:17:10
	(b) (4)	
DataPoint activated with code reason code Data required.	Amy Thomassie (b) (4)	19 Feb 2021 22:14:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 21:20:19

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:34

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:10:51
User entered empty.	Amy Thomassie (b) (4)	19 Feb 2021 22:17:10
	(b) (4)	
DataPoint activated with code reason code Data required.	Amy Thomassie (b) (4)	19 Feb 2021 22:14:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 21:20:19

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:34

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:10:51
User entered 'once (ONCE)'	Amy Thomassie (b) (4)	19 Feb 2021 22:17:10
	(b) (4)	
DataPoint activated with code reason code Data required.	Amy Thomassie (b) (4)	19 Feb 2021 22:14:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 21:20:19

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:34

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:10:51
User entered empty.	Amy Thomassie (b) (4)	19 Feb 2021 22:17:10
	(b) (4)	
DataPoint activated with code reason code Data required.	Amy Thomassie (b) (4)	19 Feb 2021 22:14:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 21:20:19

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:34

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:10:51
User entered 'Intravenous (INTRAVENOUS)'	Amy Thomassie (b) (4)	19 Feb 2021 22:17:10
	(b) (4)	
DataPoint activated with code reason code Data required.	Amy Thomassie (b) (4)	19 Feb 2021 22:14:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 21:20:19

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:10:51
User entered empty.	Amy Thomassie (b) (4)	19 Feb 2021 22:17:10
	(b) (4)	
DataPoint activated with code reason code Data required.	Amy Thomassie (b) (4)	19 Feb 2021 22:14:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 21:20:19



US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:10:51
User entered '25 Jan 2021'	Amy Thomassie (b) (4)	19 Feb 2021 22:17:10
	(b) (4)	
DataPoint activated with code reason code Data required.	Amy Thomassie (b) (4)	19 Feb 2021 22:14:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 21:20:19

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:10:51
User entered '0'	Amy Thomassie (b) (4)	19 Feb 2021 22:17:10
	(b) (4)	
DataPoint activated with code reason code Data required.	Amy Thomassie (b) (4)	19 Feb 2021 22:14:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 21:20:19

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:34

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:10:51
User entered 'No (N)'	Amy Thomassie (b) (4)	19 Feb 2021 22:17:10
	(b) (4)	
DataPoint activated with code reason code Data required.	Amy Thomassie (b) (4)	19 Feb 2021 22:14:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 21:20:19

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:34

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:10:51
User entered '25 Jan 2021'	Amy Thomassie (b) (4)	19 Feb 2021 22:17:10
	(b) (4)	
DataPoint activated with code reason code Data required.	Amy Thomassie (b) (4)	19 Feb 2021 22:14:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 21:20:19

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:10:51
User entered 'No (N)'	Amy Thomassie (b) (4)	19 Feb 2021 22:17:10
	(b) (4)	
DataPoint activated with code reason code Data required.	Amy Thomassie (b) (4)	19 Feb 2021 22:14:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 21:20:19

US3362099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:15:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 22:17:10
DataPoint activated with code reason code Data required.	Amy Thomassie (b) (4)	19 Feb 2021 22:14:42
DataPoint inactivated with code reason code Data not required.	(b) (4), (b) (6)	05 Jan 2021 21:20:19

US3362099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:15:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 22:17:10
DataPoint activated with code reason code Data required.	Amy Thomassie (b) (4)	19 Feb 2021 22:14:42
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:20:19

US3362099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 17:15:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 22:17:10
DataPoint activated with code reason code Data required.	Amy Thomassie (b) (4)	19 Feb 2021 22:14:42
DataPoint inactivated with code reason code Data not required.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 21:20:19



US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN;GLUCOSE, PRODUCTSYNONYM: CEFAZOLIN;DEXTROSE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Mar 2021 07:25:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:25:56
Data point term sent to Coder	System	18 Mar 2021 21:19:24
User entered 'CEFAZOLIN in dextrose' reason for change: Data Entry Error	Alexandra Caillouet (b) (4)	18 Mar 2021 21:18:52
User entered 'cefazolin'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:18:40

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:15:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:18:40

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Left Hip Fracture'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:18:40

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:15:34**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '2/100'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:18:40

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:15:34**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Other (OTHER)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:18:40

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'g/mL'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:18:40

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'three times daily (TID)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:18:40

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:18:40



**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:15:34**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:18:40

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:18:40

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '27 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:18:40

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '0'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:18:40

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:15:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:18:40

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:15:34**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '27 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:18:40

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:25
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:18:40

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:15:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:25
User entered '3'	System	18 Mar 2021 21:18:40



**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:15:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:25
User entered '1'	System	18 Mar 2021 21:18:40

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 17:15:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:25
User entered '804 (804)'	System	18 Mar 2021 21:18:40

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 07:41:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 07:41:00
Data point term sent to Coder	System	18 Mar 2021 21:20:26
User entered 'morphine'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:20:09

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:15:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:20:09

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Left hip fracture'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:20:09

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:15:34**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '4/1'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:20:09

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:15:34**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Other (OTHER)'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:20:09

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:34

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'mg/ml'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:20:09



US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:34

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'once (ONCE)'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:20:09

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:34

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	Alexandra Caillouet (b) (4)	18 Mar 2021 21:20:09

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:34

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Intravenous (INTRAVENOUS)'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:20:09

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	Alexandra Caillouet (b) (4)	18 Mar 2021 21:20:09

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '26 Jan 2021'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:20:09

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:34

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '0'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:20:09

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:15:34**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:20:09

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:15:34**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '26 Jan 2021'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:20:09



US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:20:09

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:15:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 21:20:09

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:15:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 21:20:09

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 17:15:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Mar 2021 21:20:09

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:34

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Mar 2021 07:42:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:42:12
Data point term sent to Coder	System	18 Mar 2021 21:22:32
User entered 'Ondansetron'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:22:07

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:15:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:22:07

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Left hip fracture'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:22:07

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:15:34**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '4/2'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:22:07



**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:15:34**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Other (OTHER)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:22:07

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'mg/mL'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:22:07

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'once (ONCE)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:22:07

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:22:07

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:15:34**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:22:07

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:22:07

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '26 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:22:07

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '0'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:22:07



**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:15:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:22:07

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:15:34**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '26 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:22:07

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:15:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:02
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:22:07

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:15:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:02
User entered empty.	System	18 Mar 2021 21:22:07

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 17:15:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:02
User entered empty.	System	18 Mar 2021 21:22:07

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:15:34

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:02
User entered empty.	System	18 Mar 2021 21:22:07

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: CALCIUM CHLORIDE;POTASSIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGERS - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	18 Mar 2021 21:39:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	(b) (4)	
Data point term sent to Coder	System	18 Mar 2021 21:24:34
User entered 'Lactated Ringers'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:04

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:15:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:04



US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Left hip Fracture'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:04

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:15:34**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '1000'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:04

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:15:34**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'mL (mL)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:04

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:04

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'other (OTHER)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:04

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'continuous'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:04

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Intravenous (INTRAVENOUS)'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:04

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:04



**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '26 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:04

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '0'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:04

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:15:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:04

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:15:34**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '28 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:04

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:10
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:04

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:15:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:10
User entered empty.	System	18 Mar 2021 21:24:04

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:15:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:10
User entered empty.	System	18 Mar 2021 21:24:04

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 17:15:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:10
User entered empty.	System	18 Mar 2021 21:24:04



US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 21:26:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 21:26:53
Data point term sent to Coder	System	18 Mar 2021 21:25:36
User entered 'acetaminophen'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:53

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:15:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:53

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'left hip fracture'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:53

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:15:34**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '325'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:53

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'mg (mg)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:53

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	(b) (4)	
	Alexandra Caillouet	18 Mar 2021 21:24:53
	(b) (4)	

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'four times daily (QID)'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:53

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	(b) (4)	
	Alexandra Caillouet	18 Mar 2021 21:24:53
	(b) (4)	



**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:15:34**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Oral (ORAL)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:53

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	(b) (4)	
	Alexandra Caillouet	18 Mar 2021 21:24:53
	(b) (4)	

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '26 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:53

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '0'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:53

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:15:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:53

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:15:34**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '28 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:53

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:49
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:24:53

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:15:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:49
User entered '4'	System	18 Mar 2021 21:24:53



**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:15:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:49
User entered '1'	System	18 Mar 2021 21:24:53

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 17:15:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:06:49
User entered '804 (804)'	System	18 Mar 2021 21:24:53

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;HYDROCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Mar 2021 07:34:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:34:59
Data point term sent to Coder	System	18 Mar 2021 21:26:36
User entered 'hydrocodone-acetaminophen'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:26:03

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:15:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:26:03

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Left hip fracture'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:26:03

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:15:34**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '7.5/325'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:26:03

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'mg (mg)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:26:03

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	(b) (4)	
	Alexandra Caillouet	18 Mar 2021 21:26:03
	(b) (4)	



US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'as needed (PRN)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:26:03

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	(b) (4)	
	Alexandra Caillouet	18 Mar 2021 21:26:03
	(b) (4)	

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:15:34**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Oral (ORAL)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:26:03

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	(b) (4)	
	Alexandra Caillouet	18 Mar 2021 21:26:03
	(b) (4)	

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '26 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:26:03

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '0'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:26:03

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:15:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:26:03

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:15:34**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '27 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:26:03



US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:38
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:26:03

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:15:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:38
User entered empty.	System	18 Mar 2021 21:26:03

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:15:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:38
User entered empty.	System	18 Mar 2021 21:26:03

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 09 Jun 2021 17:15:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:38
User entered empty.	System	18 Mar 2021 21:26:03

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Mar 2021 07:34:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:34:59
Data point term sent to Coder	System	18 Mar 2021 21:27:37
User entered 'Hydromorphone'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:27:14

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:15:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:27:14

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Left hip fracture'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:27:14

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:15:34**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '0.2/0.1'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:27:14



**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:15:34**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Other (OTHER)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:27:14

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'mg/mL'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:27:14

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'other (OTHER)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:27:14

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'every 5 minutes as needed'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:27:14

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:34

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:27:14

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:27:14

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '26 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:27:14

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '0'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:27:14



**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:15:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:27:14

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:15:34**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '27 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:27:14

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:18
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:27:14

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:34

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:18
User entered empty.	System	18 Mar 2021 21:27:14

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:15:34

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:18
User entered empty.	System	18 Mar 2021 21:27:14

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 09 Jun 2021 17:15:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:24:18
User entered empty.	System	18 Mar 2021 21:27:14

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Mar 2021 07:38:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:38:02
Data point term sent to Coder	System	18 Mar 2021 21:30:40
User entered 'Melatonin'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:29:42

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:15:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:29:42



US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Left hip fracture'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:29:42

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:15:34**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '3'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:29:42

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:15:34**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'mg (mg)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:29:42

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:15:34**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	(b) (4)	
	Alexandra Caillouet	18 Mar 2021 21:29:42
	(b) (4)	

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:15:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'once daily (QD)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:29:42

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:15:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	(b) (4)	
	Alexandra Caillouet	18 Mar 2021 21:29:42
	(b) (4)	

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:15:34**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Oral (ORAL)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:29:42

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:15:34**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:29:42



**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '26 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:29:42

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '0'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:29:42

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:15:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:29:42

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:15:34**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '27 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:29:42

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:15:34**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:46
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:29:42

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:15:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:46
User entered '1'	System	18 Mar 2021 21:29:42

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:15:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:46
User entered '1'	System	18 Mar 2021 21:29:42

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 09 Jun 2021 17:15:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:46
User entered '804 (804)'	System	18 Mar 2021 21:29:42



US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Mar 2021 07:41:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:41:01
Data point term sent to Coder	System	18 Mar 2021 21:32:56
User entered 'morphine'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:32:30

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:15:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:32:30

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:15:34**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Left hip fracture'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:32:30

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:15:34

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '2/0.5'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:32:30

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:15:34**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Other (OTHER)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:32:30

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:15:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'mg/mL'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:32:30

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:15:34**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'other (OTHER)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:32:30

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:15:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Every 4 hours as needed'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:32:30



**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:15:34**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Intravenous (INTRAVENOUS)'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:32:30

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:15:34**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	Alexandra Caillouet (b) (4)	18 Mar 2021 21:32:30

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '26 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:32:30

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '0'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:32:30

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:15:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:32:30

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:15:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '28 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:32:30

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:51
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:32:30

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:15:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:51
User entered empty.	System	18 Mar 2021 21:32:30



**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:15:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:51
User entered empty.	System	18 Mar 2021 21:32:30

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 09 Jun 2021 17:15:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:51
User entered empty.	System	18 Mar 2021 21:32:30

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:15:34

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN W/OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Mar 2021 07:42:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 07:42:13
Data point term sent to Coder	System	18 Mar 2021 21:33:57
User entered 'Oxycodone-acetaminophen'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:33:30

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:15:34**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:33:30

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:15:34

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Left hip fracture'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:33:30

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:15:34**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '7.5/325'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:33:30

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:15:34

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'mg (mg)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:33:30

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:15:34

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	(b) (4)	
	Alexandra Caillouet	18 Mar 2021 21:33:30
	(b) (4)	



US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:15:34

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'as needed (PRN)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:33:30

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:15:34

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	(b) (4)	
	Alexandra Caillouet	18 Mar 2021 21:33:30
	(b) (4)	

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:15:34**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Oral (ORAL)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:33:30

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:15:34

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:33:30

US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:15:34

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '26 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:33:30

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:15:34**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '0'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:33:30

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:15:34**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:33:30

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:15:34**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '27 Jan 2021'	(b) (4) Alexandra Caillouet (b) (4)	18 Mar 2021 21:33:30



US3362099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:15:34

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:55
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:05
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'No (N)'	Alexandra Caillouet (b) (4)	18 Mar 2021 21:33:30

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:15:34**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:55
User entered empty.	System	18 Mar 2021 21:33:30

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:15:34**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:55
User entered empty.	System	18 Mar 2021 21:33:30

**US3362099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 09 Jun 2021 17:15:34**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 15:07:55
User entered empty.	System	18 Mar 2021 21:33:30

US3362099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:15:34

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:00:16
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:21
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
DataPoint Un-verified.	(b) (4)	
	Alexandra Caillouet	18 Mar 2021 20:44:56
User entered 'Yes (Y)' reason for change: Data	(b) (4)	
Entry Error	Alexandra Caillouet	18 Mar 2021 20:44:56
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:13:25
User entered 'No (N)'	(b) (4), (b) (6)	11 Aug 2020 15:02:34

US3362099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:15:34

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered '26 Jan 2021'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:45:22

US3362099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:15:34

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Cannulated screw fixation of left femoral fracture'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:45:22

US3362099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:15:34

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered 'Adverse Event (AE)'	Alexandra Caillouet (b) (4)	18 Mar 2021 20:45:22



US3362099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:15:34

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	12 Apr 2021 16:20:42
User signature succeeded.	Jordan Whatley (b) (4)	09 Apr 2021 00:50:15
User entered empty.	Alexandra Caillouet (b) (4)	18 Mar 2021 20:45:22

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered		
'USA-US112-2021-MRNA-1273-P301000010'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'Yes (Y)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'Yes (Y)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38



**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'Jordan'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'Whatley'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered '5326 O'donovan dr'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'baton rouge'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered '70808'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'US'	System	22 Feb 2021 20:16:08

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Apr 2021 20:04:19
User entered '3'	System	22 Mar 2021 16:30:42
User entered '2'	System	19 Mar 2021 15:20:31
User entered '1'	System	22 Feb 2021 20:16:08



**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered		
'USA-US112-2021-MRNA-1273-P301000010'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'Yes (Y)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'Yes (Y)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38



**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'Jordan'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'Whatley'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered '5326 O'donovan dr'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'baton rouge'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered '70808'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'US'	System	22 Feb 2021 20:16:08

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Apr 2021 20:04:19
User entered '3'	System	22 Mar 2021 16:30:42
User entered '2'	System	19 Mar 2021 15:20:31
User entered '1'	System	22 Feb 2021 20:16:08

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 17:15:34**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:08:10
User entered '22/Feb/2021 15:16'	System	22 Feb 2021 20:16:08



US3362099

Folder: SAE USA-US112-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:15:34

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.		22 Feb 2021 20:16:12
User entered '1'		22 Feb 2021 20:16:08

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered		
'USA-US112-2021-MRNA-1273-P301000010'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'Yes (Y)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'Yes (Y)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38



**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'Jordan'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'Whatley'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered '5326 O'donovan dr'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'baton rouge'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered '70808'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'US'	System	22 Feb 2021 20:16:08

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Apr 2021 20:04:19
User entered '3'	System	22 Mar 2021 16:30:42
User entered '2'	System	19 Mar 2021 15:20:31
User entered '1'	System	22 Feb 2021 20:16:08



**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 17:15:34**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:15:26
User entered '19/Mar/2021 11:20'	System	19 Mar 2021 15:20:31

US3362099

Folder: SAE USA-US112-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:15:34

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:15:26
Reviewed for Safety.		02 Apr 2021 20:04:07
User entered '1'		19 Mar 2021 15:20:31

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered		
'USA-US112-2021-MRNA-1273-P301000010'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'Yes (Y)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'Yes (Y)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38



**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'Jordan'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'Whatley'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered '5326 O'donovan dr'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'baton rouge'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered '70808'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'US'	System	22 Feb 2021 20:16:08



**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Apr 2021 20:04:19
User entered '3'	System	22 Mar 2021 16:30:42
User entered '2'	System	19 Mar 2021 15:20:31
User entered '1'	System	22 Feb 2021 20:16:08

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 17:15:34**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:15:26
User entered '22/Mar/2021 12:30'	System	22 Mar 2021 16:30:42

US3362099

Folder: SAE USA-US112-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:15:34

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:15:26
Reviewed for Safety.		02 Apr 2021 20:04:07
User entered 'I'		22 Mar 2021 16:30:42

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered		
'USA-US112-2021-MRNA-1273-P301000010'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'Yes (Y)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'Yes (Y)'	System	22 Feb 2021 20:15:38



**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'No (N)'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'Jordan'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'Whatley'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered '5326 O'donovan dr'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'baton rouge'	System	22 Feb 2021 20:15:38

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered '70808'	System	22 Feb 2021 20:15:38



**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Mar 2021 19:08:10
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 20:16:12
User entered 'US'	System	22 Feb 2021 20:16:08

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 17:15:34**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	02 Apr 2021 20:04:19
User entered '3'	System	22 Mar 2021 16:30:42
User entered '2'	System	19 Mar 2021 15:20:31
User entered '1'	System	22 Feb 2021 20:16:08

**US3362099**

**Folder: SAE USA-US112-2021-MRNA-1273-P301000010**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 17:15:34**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 18:15:26
User entered '02/Apr/2021 20:04'	System	02 Apr 2021 20:04:19

US3362099

Folder: SAE USA-US112-2021-MRNA-1273-P301000010

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:15:34

**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.	Jordan Whatley (b) (4)	24 Apr 2021 00:12:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 18:15:26
User entered 'I'	(b) (4), (b) (6)	02 Apr 2021 20:04:19