

US3862099 (Prod: Baylor College of Medicine)

Generated By: (b) (6)

Generated On: 11 Jun 2021 15:16:15

All time stamps listed in this document are displayed in GMT

US3862099

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 14:20:37

Generated On: 11 Jun 2021 15:16:15

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Participant ID

US3862099

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

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US3862099

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

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

Visit date (dd MMM yyyy)	31 AUG 2020
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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	SCRN
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US3862099

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Date of Birth (MMM yyyy)	(b) (6) 1969
Age	51
Age Units	YEARS
Age (Derived)	51
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	False
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	True

US3862099

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Date of Informed Consent ( <i>dd MMM yyyy</i> )	31 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3862099

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 29 Mar 2021 15:56:27

Generated On: 11 Jun 2021 15:16:15

Condition	HIV
Start date (dd MMM yyyy)	UN DEC 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)	DEC 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 29 Mar 2021 15:56:27

Generated On: 11 Jun 2021 15:16:15

Condition	CHRONIC HEPATITIS B
Start date (dd MMM yyyy)	UN FEB 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2005
Start Year (derived)	2005
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3862099

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 29 Mar 2021 15:56:27

Generated On: 11 Jun 2021 15:16:15

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

US3862099

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 29 Mar 2021 15:56:27

Generated On: 11 Jun 2021 15:16:15

Condition	GENERAL BODY ACHES
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	14:41 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 14:41
Height (xxx.x)	73.5 in
Weight (xxx.x)	254 lb
BMI (xxx.x)	33.12599 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:39:47

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:39:47

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

What was the date of randomization? (dd MMM yyyy) 31 AUG 2020

What was the participant's randomization number? 145529

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

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

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

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

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

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

Liver Disease Yes ☒ No ☐

Human Immunodeficiency Virus (HIV) infection Yes ☒ No ☐

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

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)	31 AUG 2020
Time of assessment (00:00-23:59)	14:41 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 14:41
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 AUG 2020
Time of assessment (00:00-23:59)	16:53 (24 HR)
Vital Signs Date and Time (derived)	31 AUG 2020 16:53
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

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) 31 AUG 2020

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

Treatment Date and Time (derived) 31 AUG 2020 16:23

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

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

Collection date (dd MMM yyyy)	31 AUG 2020
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Collection time (00:00-23:59)	15:39 (24 HR)
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Collection date and time (derived)	31 AUG 2020 15:39
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Collection date (dd MMM yyyy)			31 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:15	31 AUG 2020 15:15
Nasopharyngeal Swab 2	No		

US3862099

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**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

97.8 °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

31 AUG 2020 16:55

PC Open Date & Time

31 AUG 2020 16:43

PC Close Date & Time

31 AUG 2020 19:13

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**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 98.8 °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	31 AUG 2020 21:42
PC Open Date & Time	31 AUG 2020 20:08
PC Close Date & Time	01 SEP 2020 11:59

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:16:15

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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

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

01 SEP 2020 21:42

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**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

97.9 °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

03 SEP 2020 09:03

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 19:03

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**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

97.8 °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

04 SEP 2020 22:32

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**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

05 SEP 2020 12:26

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**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

31 AUG 2020 16:55

PC Open Date & Time

31 AUG 2020 16:43

PC Close Date & Time

31 AUG 2020 19:13

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**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

31 AUG 2020 21:44

PC Open Date & Time

31 AUG 2020 20:08

PC Close Date & Time

01 SEP 2020 11:59

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:16:15

**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

01 SEP 2020 21:42

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**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

03 SEP 2020 09:03

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**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

03 SEP 2020 19:03

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**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

04 SEP 2020 22:32

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**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

05 SEP 2020 12:27

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**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 ☐

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 16:56
PC Open Date & Time	31 AUG 2020 16:43
PC Close Date & Time	31 AUG 2020 19:13

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**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 ☐

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

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

No ☒

Yes ☐

PC Time stamp	31 AUG 2020 21:45
PC Open Date & Time	31 AUG 2020 20:08
PC Close Date & Time	01 SEP 2020 11:59

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 21:43
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

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 ☒

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 09:04
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:16:15

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:16:15

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 19:03
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 22:33
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

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

53 of 2625

EAB) (1725)

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 12:27
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:16:15

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

55 of 2625

EAB) (1725)

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:16:15

Yes ☐

PC Time stamp

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3862099

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 9 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3862099

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862099

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:39:46

Generated On: 11 Jun 2021 15:16:15

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3862099

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:39:46

Generated On: 11 Jun 2021 15:16:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862099

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3862099

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862099

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

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)	28 SEP 2020
Time of assessment (00:00-23:59)	14:41 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 14:41
Temperature (xxx.x)	098.4 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	078 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	018 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	070 mmHg
Diastolic Blood Pressure units	MMHG

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

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)	28 SEP 2020
Time of assessment (00:00-23:59)	16:38 (24 HR)
Vital Signs Date and Time (derived)	28 SEP 2020 16:38
Temperature (xxx.x)	097.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	077 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	018 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	080 mmHg
Diastolic Blood Pressure units	MMHG

US3862099

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 SEP 2020

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

US3862099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

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) 28 SEP 2020

What was the treatment time? (00:00-23:59) 16:03 (24 HR)

Treatment Date and Time (derived) 28 SEP 2020 16:03

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

What was the frequency of the study treatment dosing? ONCE

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

US3862099

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

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

Collection date (dd MMM yyyy)	28 SEP 2020
-------------------------------	-------------

Collection time (00:00-23:59)	15:23 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	28 SEP 2020 15:23
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US3862099

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Collection date (dd MMM yyyy)			28 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	No		
Nasopharyngeal Swab 2	Yes	15:15	28 SEP 2020 15:15

US3862099

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**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

97.5 °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

28 SEP 2020 18:10

PC Open Date & Time

28 SEP 2020 16:23

PC Close Date & Time

28 SEP 2020 18:53

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**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

97.5 °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	29 SEP 2020 07:56
PC Open Date & Time	28 SEP 2020 19:48
PC Close Date & Time	29 SEP 2020 11:59

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:16:15

**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

97.5 °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

29 SEP 2020 12:00

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**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

97.5 °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

30 SEP 2020 23:05

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**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

98.0 °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 01 OCT 2020 12:01

PC Open Date & Time 01 OCT 2020 12:00

PC Close Date & Time 02 OCT 2020 11:59

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**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

97.5 °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

02 OCT 2020 12:55

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**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

03 OCT 2020 18:56

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	97.5 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	True
PC Time Stamp	04 OCT 2020 12:00
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 8

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 07:08

PC Open Date & Time

05 OCT 2020 12:00

PC Close Date & Time

06 OCT 2020 11:59

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**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

28 SEP 2020 18:11

PC Open Date & Time

28 SEP 2020 16:23

PC Close Date & Time

28 SEP 2020 18:53

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**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

29 SEP 2020 07:57

PC Open Date & Time

28 SEP 2020 19:48

PC Close Date & Time

29 SEP 2020 11:59

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:16:15

**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

29 SEP 2020 12:01

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**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

30 SEP 2020 23:06

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**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

01 OCT 2020 12:01

PC Open Date & Time

01 OCT 2020 12:00

PC Close Date & Time

02 OCT 2020 11:59

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**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

02 OCT 2020 12:55

PC Open Date & Time

02 OCT 2020 12:00

PC Close Date & Time

03 OCT 2020 11:59

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**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

03 OCT 2020 18:56

PC Open Date & Time

03 OCT 2020 12:00

PC Close Date & Time

04 OCT 2020 11:59

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**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

04 OCT 2020 12:01

PC Open Date & Time

04 OCT 2020 12:00

PC Close Date & Time

05 OCT 2020 11:59

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**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 ☐

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

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

No ☒

Yes ☐

PC Time stamp	28 SEP 2020 18:11
PC Open Date & Time	28 SEP 2020 16:23
PC Close Date & Time	28 SEP 2020 18:53

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**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 ☐

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

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

No ☒

Yes ☐

PC Time stamp	29 SEP 2020 07:57
PC Open Date & Time	28 SEP 2020 19:48
PC Close Date & Time	29 SEP 2020 11:59

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 12:01
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 23:06
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:16:15

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 ☒

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EAB) (1725)

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:16:15

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

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

TIMEPOINT

DAY 5

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

Yes <input type="checkbox"/>	
PC Time stamp	02 OCT 2020 12:56
PC Open Date & Time	02 OCT 2020 12:00
PC Close Date & Time	03 OCT 2020 11:59

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

Yes <input type="checkbox"/>	
PC Time stamp	03 OCT 2020 18:56
PC Open Date & Time	03 OCT 2020 12:00
PC Close Date & Time	04 OCT 2020 11:59

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:16:15

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:16:15

Yes <input type="checkbox"/>	
PC Time stamp	04 OCT 2020 12:01
PC Open Date & Time	04 OCT 2020 12:00
PC Close Date & Time	05 OCT 2020 11:59

US3862099

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Jun 2021 15:16:15

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION (doctor visit, other)</b> for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	06 OCT 2020 07:08
PC Open Date & Time	05 OCT 2020 12:00
PC Close Date & Time	06 OCT 2020 11:59

US3862099

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 6 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3862099

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862099

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3862099

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862099

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3862099

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862099

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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

US3862099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 OCT 2020
Time of assessment (00:00-23:59)	14:25 (24 HR)
Vital Signs Date and Time (derived)	28 OCT 2020 14:25
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	83 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862099

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

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.*

US3862099

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 OCT 2020
Collection time (00:00-23:59)	14:52 (24 HR)
Collection date and time (derived)	28 OCT 2020 14:52

US3862099

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:39:47

Generated On: 11 Jun 2021 15:16:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

<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	02 NOV 2020 11:34:39
Patient Cloud Open Date & Time	31 OCT 2020 00:01
Patient Cloud Close Date & Time	04 NOV 2020 23:59

US3862099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 NOV 2020 12:00:37
Patient Cloud Open Date & Time	07 NOV 2020 00:01
Patient Cloud Close Date & Time	11 NOV 2020 23:59

US3862099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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 <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"/>

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

<b>TIMEPOINT</b>	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 NOV 2020 20:04:08
Patient Cloud Open Date & Time	18 NOV 2020 00:01
Patient Cloud Close Date & Time	22 NOV 2020 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

TIMEPOINT	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 00:01:28
Patient Cloud Open Date & Time	25 NOV 2020 00:01
Patient Cloud Close Date & Time	29 NOV 2020 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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[Patient Cloud Close Date & Time](#)

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06 DEC 2020 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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

09 DEC 2020 00:01:34

Patient Cloud Open Date & Time

09 DEC 2020 00:01

Patient Cloud Close Date & Time

13 DEC 2020 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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	16 DEC 2020 00:59:18
Patient Cloud Open Date & Time	16 DEC 2020 00:01
Patient Cloud Close Date & Time	20 DEC 2020 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2020 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

30 DEC 2020 00:01

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[Patient Cloud Close Date & Time](#)

03 JAN 2021 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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[Patient Cloud Open Date & Time](#)

06 JAN 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 JAN 2021 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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

13 JAN 2021 14:53:25

Patient Cloud Open Date & Time

13 JAN 2021 00:01

Patient Cloud Close Date & Time

17 JAN 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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

20 JAN 2021 00:01:47

Patient Cloud Open Date & Time

20 JAN 2021 00:01

Patient Cloud Close Date & Time

24 JAN 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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

27 JAN 2021 00:01:30

Patient Cloud Open Date & Time

27 JAN 2021 00:01

Patient Cloud Close Date & Time

31 JAN 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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

03 FEB 2021 00:32:47

Patient Cloud Open Date & Time

03 FEB 2021 00:01

Patient Cloud Close Date & Time

07 FEB 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 00:01:44
Patient Cloud Open Date & Time	10 FEB 2021 00:01
Patient Cloud Close Date & Time	14 FEB 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 FEB 2021 00:08:21

Patient Cloud Open Date & Time

17 FEB 2021 00:01

Patient Cloud Close Date & Time

21 FEB 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 00:01:26

Patient Cloud Open Date & Time

24 FEB 2021 00:01

Patient Cloud Close Date & Time

28 FEB 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAR 2021 00:02:51

Patient Cloud Open Date & Time

03 MAR 2021 00:01

Patient Cloud Close Date & Time

07 MAR 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 00:03:11

Patient Cloud Open Date & Time

10 MAR 2021 00:01

Patient Cloud Close Date & Time

14 MAR 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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	17 MAR 2021 00:30:25
Patient Cloud Open Date & Time	17 MAR 2021 00:01
Patient Cloud Close Date & Time	21 MAR 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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

24 MAR 2021 00:02:35

Patient Cloud Open Date & Time

24 MAR 2021 00:01

Patient Cloud Close Date & Time

28 MAR 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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

03 APR 2021 17:59:28

Patient Cloud Open Date & Time

31 MAR 2021 00:01

Patient Cloud Close Date & Time

04 APR 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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 APR 2021 00:46:20
Patient Cloud Open Date & Time	07 APR 2021 00:01
Patient Cloud Close Date & Time	11 APR 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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 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	14 APR 2021 00:02:49
Patient Cloud Open Date & Time	14 APR 2021 00:01
Patient Cloud Close Date & Time	18 APR 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

<b>TIMEPOINT</b>	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 APR 2021 00:02:31
Patient Cloud Open Date & Time	21 APR 2021 00:01
Patient Cloud Close Date & Time	25 APR 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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

28 APR 2021 00:02:20

Patient Cloud Open Date & Time

28 APR 2021 00:01

Patient Cloud Close Date & Time

02 MAY 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 250

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

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

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

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

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

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

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	05 MAY 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 MAY 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

19 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 MAY 2021 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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 ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 292

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

16 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

20 JUN 2021 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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"/>

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

23 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

27 JUN 2021 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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[Patient Cloud Open Date & Time](#)

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30 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 JUL 2021 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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 ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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[Patient Cloud Open Date & Time](#)

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07 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 JUL 2021 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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"/>

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	21 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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"/>

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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="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"/>

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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11 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 AUG 2021 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

18 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 AUG 2021 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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 ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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[Patient Cloud Open Date & Time](#)

01 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 SEP 2021 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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[Patient Cloud Open Date & Time](#)

08 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 SEP 2021 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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15 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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19 SEP 2021 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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[Patient Cloud Close Date & Time](#)

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26 SEP 2021 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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 ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

03 OCT 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 404

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

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

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

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

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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[Patient Cloud Open Date & Time](#)

06 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 OCT 2021 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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"/>

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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 ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

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 ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

31 OCT 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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[Patient Cloud Open Date & Time](#)

03 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

07 NOV 2021 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 NOV 2021 23:59
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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

28 NOV 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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"/>

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	01 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	05 DEC 2021 23:59
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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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"/>

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 DEC 2021 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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 <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"/>

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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[Patient Cloud Close Date & Time](#)

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02 JAN 2022 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 495

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

No ☐  
Yes ☐

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

No ☐  
Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐  
Yes ☐

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

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

Chills

Cough

Shortness of breath

Difficulty breathing

Fatigue

Muscle aches

Body aches

Headache

New loss of taste

New loss of smell

Sore throat

Congestion

Runny nose

Nausea

Vomiting

Diarrhea

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐  
Yes ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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[Patient Cloud Close Date & Time](#)

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30 JAN 2022 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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 ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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[Patient Cloud Close Date & Time](#)

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06 FEB 2022 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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"/>

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

09 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 FEB 2022 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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 ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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[Patient Cloud Close Date & Time](#)

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20 FEB 2022 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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="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"/>

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

27 FEB 2022 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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 ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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[Patient Cloud Close Date & Time](#)

06 MAR 2022 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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 ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

[Patient Cloud Close Date & Time](#)

13 MAR 2022 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 565

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

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

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

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

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

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

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 572

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

23 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 MAR 2022 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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 ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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[Patient Cloud Open Date & Time](#)

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30 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 APR 2022 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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[Patient Cloud Close Date & Time](#)

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10 APR 2022 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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 ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

17 APR 2022 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

24 APR 2022 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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"/>

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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"/>

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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11 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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15 MAY 2022 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUN 2022 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUN 2022 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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 ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 JUL 2022 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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 ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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[Patient Cloud Open Date & Time](#)

06 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 JUL 2022 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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"/>

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 JUL 2022 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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"/>

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JUL 2022 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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 ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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[Patient Cloud Close Date & Time](#)

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31 JUL 2022 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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 ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

04 SEP 2022 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

11 SEP 2022 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

02 OCT 2022 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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[Patient Cloud Close Date & Time](#)

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09 OCT 2022 23:59

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US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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 ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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 ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**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 ☐

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

30 OCT 2022 23:59

US3862099

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

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

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

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[Patient Cloud Close Date & Time](#)

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06 NOV 2022 23:59

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US3862099

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 11 Jun 2021 15:16:15

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 00:03:24

US3862099

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:29:15

Generated On: 11 Jun 2021 15:16:15

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 NOV 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3862099

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:29:15

Generated On: 11 Jun 2021 15:16:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862099

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3862099

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862099

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3862099

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862099

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:20:39

Generated On: 11 Jun 2021 15:16:15

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3862099

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:20:39

Generated On: 11 Jun 2021 15:16:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862099

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:20:39

Generated On: 11 Jun 2021 15:16:15

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

Visit date (dd MMM yyyy)	25 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3862099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 14:20:39

Generated On: 11 Jun 2021 15:16:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 MAR 2021
Time of assessment (00:00-23:59)	14:57 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 14:57
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862099

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:20:39

Generated On: 11 Jun 2021 15:16:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 MAR 2021

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

US3862099

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:20:39

Generated On: 11 Jun 2021 15:16:15

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

Collection date (dd MMM yyyy)	25 MAR 2021
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Collection time (00:00-23:59)	15:10 (24 HR)
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Collection date and time (derived)	25 MAR 2021 15:10
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US3862099

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:20:39

Generated On: 11 Jun 2021 15:16:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862099

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3862099

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3862099**

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

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

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*

**US3862099**

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

**Form: Continuing**

**Generated On: 11 Jun 2021 15:16:15**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3862099

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 11 Jun 2021 15:16:15

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

**US3862099**

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

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

**Generated On: 11 Jun 2021 15:16:15**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3862099

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

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

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Visit date (dd MMM yyyy)	13 JAN 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"/>

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Folder OID	UNBLND_DECIDE
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US3862099

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

Date of updated informed consent ( <i>dd MMM yyyy</i> )	13 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	13 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3862099

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

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

US3862099

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 JAN 2021
Time of assessment (00:00-23:59)	14:36 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 14:36
Temperature (xxx.x)	98.3 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	71 mmHg
Diastolic Blood Pressure units	MMHG

US3862099

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 JAN 2021
Time of assessment (00:00-23:59)	16:08 (24 HR)
Vital Signs Date and Time (derived)	13 JAN 2021 16:08
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3862099

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 JAN 2021

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

US3862099

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 13 JAN 2021

What was the treatment time? (00:00-23:59) 15:36 (24 HR)

Treatment Date and Time (derived) 13 JAN 2021 15:36

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

US3862099

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

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

Collection date (dd MMM yyyy)	13 JAN 2021
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Collection time (00:00-23:59)	14:44 (24 HR)
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Collection date and time (derived)	13 JAN 2021 14:44
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US3862099

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

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

Collection date (dd MMM yyyy)	13 JAN 2021
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Collection time (00:00 - 23:59)	14:42
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Collection Date and Time (derived)	13 JAN 2021 14:42
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US3862099

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862099

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:20:39

Generated On: 11 Jun 2021 15:16:15

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 20 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3862099

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:20:39

Generated On: 11 Jun 2021 15:16:15

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

US3862099

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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	OLD29

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

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)	12 FEB 2021
Time of assessment (00:00-23:59)	11:47 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 11:47
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

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)	12 FEB 2021
Time of assessment (00:00-23:59)	13:11 (24 HR)
Vital Signs Date and Time (derived)	12 FEB 2021 13:11
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3862099

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 FEB 2021

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

US3862099

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

Was study treatment given? Yes ☒  
No ☐

If No, reason not given

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

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

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

What was the treatment date? (dd MMM yyyy) 12 FEB 2021

What was the treatment time? (00:00-23:59) 12:41 (24 HR)

Treatment Date and Time (derived) 12 FEB 2021 12:41

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

US3862099

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862099

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:20:39

Generated On: 11 Jun 2021 15:16:15

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 19 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3862099

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:20:39

Generated On: 11 Jun 2021 15:16:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862099

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3862099

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 MAR 2021
Time of assessment (00:00-23:59)	14:57 (24 HR)
Vital Signs Date and Time (derived)	25 MAR 2021 14:57
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	111 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862099

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 MAR 2021

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

US3862099

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

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

Collection date (dd MMM yyyy)	25 MAR 2021
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Collection time (00:00-23:59)	15:10 (24 HR)
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Collection date and time (derived)	25 MAR 2021 15:10
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US3862099

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Mar 2021 15:15:31

Generated On: 11 Jun 2021 15:16:15

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3862099

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

AEID

Adverse event

RINGING IN RIGHT EAR

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)

12 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

19 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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EAB) (1725)

US3862099

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

Persistent or significant disability or incapacity False

Congenital anomaly or birth defect False

Other medically important event False

Relationship to investigational product Not Related ☒

Related ☐

Not Applicable ☐

Relationship to Study Procedure Not Related ☒

Related ☐

Not Applicable ☐

Action taken with investigational product None ☐

Dose Delayed ☐

Investigational Product ☐

Withdrawn ☐

Not Applicable ☒

Other action taken (check all that apply)

None True

Concomitant Medication False

Concomitant Procedure False

Outcome Fatal ☐

Not Recovered/Not Resolved ☐

Recovered/Resolved ☒

Recovered/Resolved with ☐

Sequelae ☐

Recovering/Resolving ☐

Unknown ☐

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Narrative

SUBJECT EXPERIENCED  
INTERMITTENT RINGING IN HIS  
RIGHT EAR. THE RINGING  
SUBSIDED ON OCTOBER 19TH  
WITHOUT ANY  
INTERVENTIONS,  
MEDICATIONS, OR DOCTOR  
FOLLOW-UP.

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Data signed:** (b) (4) 28 Apr 2021 22:04:02

**Generated On: 11 Jun 2021 15:16:15**

Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	0
Admitted to ICU Derived (CSA Programming Field Only)	

US3862099

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

AEID

Adverse event

SUPERFICIAL PAIN ON RIGHT  
FRONTAL TO TEMPORAL  
REGION OF HEAD

Was this a medically-attended AE? Yes ☐  
No ☒

Was this a Solicited Adverse Reaction? Yes ☐  
No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19? Yes ☐  
No ☒

Start date (dd MMM yyyy) 19 OCT 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing? Yes ☐  
No ☒

If not Ongoing, end date (dd MMM yyyy) 19 OCT 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity Grade 1/Mild ☒  
Grade 2/Moderate ☐  
Grade 3/Severe ☐  
Grade 4 ☐

Is the adverse event serious? Yes ☐  
No ☒

AE is serious due To (check all that apply)

Death False

Life threatening False

Requires inpatient or prolongation of existing Hospitalization False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU? Yes ☐  
No ☐  
Unknown ☐

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

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

US3862099

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

AEID	USA-US121-2021-MRNA-1273-P30 1000006
Adverse event	LEFT PROXIMAL AND DISTAL URETERAL CALCULI
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)	13 MAR 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)	14 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	14 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	15 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	356 of 2625

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

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

US3862099

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

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13 MAR 2021: SUBJECT HAD SEVERE LEFT FLANK PAIN, WENT TO ER. CT RENAL STONE PROTOCOL DONE: LEFT PROXIMAL 10MM AND DISTAL 7MM URETERAL CALCULI CAUSING OBSTRUCTION AND NON-OBSTRUCTIVE 8 MM LEFT KIDNEY STONE, MILD LEFT HYDROURETERONEPHROSIS AND PERIURETERAL AND PERINEPHRIC FAT STRANDING, NON-OBSTRUCTING LEFT NEPHROLITHIASIS. UROLOGY CONSULT DONE, UNDERWENT CYSTOSCOPY, URETEROSCOPY, LASER LITHOTRIPSY WITH STONE REMOVAL AND URETERAL STENT PLACEMENT  
15 MAR 2021: WAS DISCHARGED HOME WITH URETERAL STENT IN PLACED AND DISCHARGE MEDICATIONS. 22 MAR 2021: UROLOGIST APPOINTMENT FOR FOLLOW-UP AND PLAN FOR 8 MM KIDNEY STONE (LEFT NONOBSTRUCTING LEFT NEPHROLITHIASIS)

---

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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US3862099

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

AEID	USA-US121-2021-MRNA-1273-P30 1000006
Adverse event	NON OBSTRUCTING LEFT NEPHROLITHIASIS
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)	13 MAR 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)	11 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	14 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	15 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (4)

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 28 Apr 2021 22:04:02

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13 MAR 2021: SUBJECT HAD SEVERE LEFT FLANK PAIN, WENT TO ER. CT RENAL STONE PROTOCOL DONE: LEFT PROXIMAL 10MM AND DISTAL 7MM URETERAL CALCULI CAUSING OBSTRUCTION AND NON-OBSTRUCTIVE 8 MM LEFT KIDNEY STONE, MILD LEFT HYDROURETERONEPHROSIS AND PERIURETERAL AND PERINEPHRIC FAT STRANDING, NON-OBSTRUCTING LEFT NEPHROLITHIASIS. UROLOGY CONSULT DONE, UNDERWENT CYSTOSCOPY, URETEROSCOPY, LASER LITHOTRIPSY WITH STONE REMOVAL AND URETERAL STENT PLACEMENT  
15 MAR 2021: WAS DISCHARGED HOME WITH URETERAL STENT IN PLACED AND DISCHARGE MEDICATIONS. 22 MAR 2021: UROLOGIST APPOINTMENT FOR FOLLOW-UP AND PLAN FOR 8 MM KIDNEY STONE  
20 APR 2021. NONOBSTRUCTIVE LEFT RENAL CALCULUS REMOVED ON 11 APR 2021. MEDICAL RECORD PENDING. 19 APR 2021 URETHRAL STENT REMOVED - MEDICAL RECORD PENDING

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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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

AEID	USA-US121-2021-MRNA-1273-P30 1000006
Adverse event	LEFT FLANK PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	14 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	15 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product 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	SEE COMMENTS FOR LEFT PROXIMAL AND DISTAL URETHRAL CALCULI AE
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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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 22:04:02

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AEID

Adverse event

GROSS HEMATURIA

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)

4 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)

19 APR 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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 28 Apr 2021 22:04:02

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
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 _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

AEID

Adverse event

VOIDING DIFFICULTLY

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)

4 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)

19 APR 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

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 28 Apr 2021 22:04:02

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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 _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

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

Yes ☒

No ☐

---

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

Name of Medication PREZCOBIX

Prophylaxis Yes ☐  
No ☒

Indication HIV

Dose per administration 800/150

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN DEC 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

Name of Medication PIFELTRO

Prophylaxis Yes ☐  
No ☒

Indication HIV

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN DEC 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

Name of Medication ENTECAVIR

Prophylaxis Yes ☐  
No ☒

Indication HEPATITIS B

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN FEB 2005	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 22:04:02

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Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication GENERAL PAIN

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 22:04:02

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Name of Medication VICK'S VAPORUB

Prophylaxis Yes ☐  
No ☒

Indication FOREHEAD PAIN

Dose per administration 1

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

If dose unit is Other, specify TEASPOON

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

	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)		19 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	21 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 22:04:02

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Name of Medication ADVIL

Prophylaxis Yes ☐  
No ☒

Indication GENERAL PAIN POST  
VACCINATION  
REACTOGENICITY SYMPTOMS

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

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	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)	04 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		04 OCT 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

Name of Medication IBUPROFEN

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS POST VACCINE  
REACTOGENICITY SYMPTOMS

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

	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)	12 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		12 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

Name of Medication CEFUROXIME AXETIL

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS FOR INFECTION  
POST LAPAROSCOPIC SURGERY  
DUE TO NEPHROLITHIASIS

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

	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)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 MAR 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

Name of Medication HYDROCODONE/  
ACETAMINOPHEN

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS FOR PAIN POST  
LAPAROSCOPIC SURGERY(DUE  
TO NEPHROLITHIASIS)

Dose per administration 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

EVERY 4 HOURS AS NEEDED

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

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	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 22:04:02

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Name of Medication AZO TABLET

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS FOR PAIN POST  
LAPAROSCOPIC SURGERY (DUE  
TO NEPHROLITHIASIS)

Dose per administration 95

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

TID AS NEEDED

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

	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)	15 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 22:04:02

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Name of Medication TOLTERODINE

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXIS FOR URINARY  
SPASM

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

Name of Medication LACTATED RINGER'S INFUSION

Prophylaxis Yes ☐  
No ☒

Indication LEFT PROXIMAL AND DISTAL  
URETERAL CALCULI NON  
OBSTRUCTING LEFT  
NEPHROLITHIASIS

Dose per administration 50

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

If dose unit is Other, specify ML/HR

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 INFUSION

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 22:04:02

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	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

Name of Medication MORPHINE

Prophylaxis Yes ☐  
No ☒

Indication LEFT PROXIMAL AND DISTAL  
URETERAL CALCULI NON  
OBSTRUCTING LEFT  
NEPHROLITHIASIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY 4 HOURS AS NEEDED

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

Name of Medication PYRIDIUM

Prophylaxis Yes ☐  
No ☒

Indication LEFT PROXIMAL AND DISTAL  
URETERAL CALCULI NON  
OBSTRUCTING LEFT  
NEPHROLITHIASIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 MAR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

Name of Medication MIRALAX

Prophylaxis Yes ☐  
No ☒

Indication LEFT PROXIMAL AND DISTAL  
URETERAL CALCULI NON  
OBSTRUCTING LEFT  
NEPHROLITHIASIS

Dose per administration 17

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 MAR 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

Name of Medication SENNOSIDE DOCUSATE  
SODIUM

Prophylaxis Yes ☐  
No ☒

Indication LEFT PROXIMAL AND DISTAL  
URETERAL CALCULI NON  
OBSTRUCTING LEFT  
NEPHROLITHIASIS

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	14 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

Name of Medication SODIUM CHLORIDE 0.9 %  
INFUSION

Prophylaxis Yes ☐  
No ☒

Indication LEFT PROXIMAL AND DISTAL  
URETERAL CALCULI NON  
OBSTRUCTING LEFT  
NEPHROLITHIASIS

Dose per administration 125

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

If dose unit is Other, specify ML/HR

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 INFUSION

Route of administration Oral ☐  
Topical ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

	Subcutaneous	<input type="checkbox"/>
	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	14 MAR 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"/>	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐  
No ☒

Indication LEFT PROXIMAL AND DISTAL  
URETERAL CALCULI NON  
OBSTRUCTING LEFT  
NEPHROLITHIASIS

Dose per administration 0.4

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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

	Transdermal	<input type="checkbox"/>
	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	14 MAR 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"/>

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

Name of Medication CEFUROXIME

Prophylaxis Yes ☐  
No ☒

Indication URETHRAL STENT REMOVAL

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

	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)	19 APR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

Name of Medication CODEINE/ACETOMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication URETHRAL STENT REMOVAL

Dose per administration 30/300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

	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)		19 APR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 APR 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"/>

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 14:20:38

Generated On: 11 Jun 2021 15:16:15

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Apr 2021 14:00:54

Generated On: 11 Jun 2021 15:16:15

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
14 MAR 2021	URETERAL STENT PLACEMENT	Adverse Event	
14 MAR 2021	CYSTOSCOPY	Adverse Event	
14 MAR 2021	URETEROSCOPY	Adverse Event	
14 MAR 2021	LASER LITHOTRIPSY	Adverse Event	
11 APR 2021	NONOBSTRUCTIVE RENAL CALCULI LEFT KIDNEY REMOVAL	Adverse Event	
19 APR 2021	URETHRAL STENT REMOVAL	Adverse Event	
13 APR 2021	CT OF THE ABDOMEN AND PELVIS	Adverse Event	

US3862099

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 11 Jun 2021 15:16:15

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

US3862099

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 11 Jun 2021 15:16:15

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by  
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

SAEID	USA-US121-2021-MRNA-1273-P301000006
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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

SAEID	USA-US121-2021-MRNA-1273-P301000006
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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	18/MAR/2021 11:04
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

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

SAEID	USA-US121-2021-MRNA-1273-P301000006
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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	29/MAR/2021 06:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

SAEID	USA-US121-2021-MRNA-1273-P301000006
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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	29/MAR/2021 09:51
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

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

SAEID	USA-US121-2021-MRNA-1273-P301000006
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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	07/APR/2021 09:40
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

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

SAEID	USA-US121-2021-MRNA-1273-P301000006
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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	21/APR/2021 09:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form (6)

Data signed: (b) (4) 28 Apr 2021 22:04:02

Generated On: 11 Jun 2021 15:16:15

SAEID	USA-US121-2021-MRNA-1273-P301000006
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	THEA MARIE
Investigator's Last Name	CORDERO
Site Address: Street	ONE BAYLOR PLAZA, MS 280, ROOM 221D
Site Address: City	HOUSTON
Site Address: State	TX
Site Address: Postal Code	77030
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	26/APR/2021 08:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3862099 (Prod: Baylor College of Medicine)

**US3862099**

**Form: Participant Creation**

**Generated On: 11 Jun 2021 15:16:15**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'US3862099'	RWS_ENDPOINT	31 Aug 2020 20:09:34
	ENDPOINT (b) (4)	
	(b) (4)	

US3862099

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 15:16:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:07:11
	(b) (4)	

US3862099

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 15:16:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 20:09:35

US3862099

Folder: Screening

Form: Visit Date

Generated On: 11 Jun 2021 15:16:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:07:11
	(b) (4)	

**US3862099**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 11 Jun 2021 15:16:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered 'SCRN'	System	31 Aug 2020 21:07:11

US3862099

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:16:15

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered (b) (6) 1969'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 20:09:37

**US3862099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Jun 2021 15:16:15**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '51'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:07:25
	(b) (4)	

**US3862099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Jun 2021 15:16:15**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered 'YEARS'	System	31 Aug 2020 21:07:25

**US3862099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Jun 2021 15:16:15**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered '51'	System	31 Aug 2020 21:07:41

**US3862099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Jun 2021 15:16:15**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Male (M)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:07:25
	(b) (4)	

US3862099

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:16:15

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:07:25

US3862099

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:16:15

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User closed query 'Race has not been provided. Please correct.' (Site from System).	(b) (4)	31 Aug 2020 21:07:33
User opened query 'Race has not been provided. Please correct.' (Site from System).	System	31 Aug 2020 21:07:25
User entered '0'	Carrie Kibler (b) (4)	31 Aug 2020 21:07:25
	(b) (4)	

US3862099

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:16:15

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '0'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:07:25
	(b) (4)	

**US3862099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Jun 2021 15:16:15**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '0'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:07:25
	(b) (4)	

**US3862099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Jun 2021 15:16:15**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:07:25

**US3862099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Jun 2021 15:16:15**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '0'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:07:25

**US3862099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Jun 2021 15:16:15**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '0'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:07:25
	(b) (4)	

US3862099

Folder: Screening

Form: Demographics

Generated On: 11 Jun 2021 15:16:15

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:07:25
	(b) (4)	

**US3862099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Jun 2021 15:16:15**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '0'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:07:25
	(b) (4)	

**US3862099**

**Folder: Screening**

**Form: Demographics**

**Generated On: 11 Jun 2021 15:16:15**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '1' reason for change: Data Entry Error	(b) (4)	31 Aug 2020 21:07:33
User entered '0'	Carrie Kibler (b) (4)	31 Aug 2020 21:07:25
	(b) (4)	

US3862099

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:16:15

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '31 Aug 2020'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:07:41
	(b) (4)	

**US3862099**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Jun 2021 15:16:15**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered 'Aug 2020'	System	31 Aug 2020 21:07:41

**US3862099**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 11 Jun 2021 15:16:15**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered '2020'	System	31 Aug 2020 21:07:41

US3862099

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:16:15

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Amendment 3 (3)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:07:41
	(b) (4)	

US3862099

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:16:15

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:07:41
	(b) (4)	

US3862099

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:16:15

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:07:41
	(b) (4)	

US3862099

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:16:15

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:07:41
	(b) (4)	

US3862099

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:16:15

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:07:41
	(b) (4)	

US3862099

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:16:15

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 20:09:35

US3862099

Folder: Screening

Form: Enrollment

Generated On: 11 Jun 2021 15:16:15

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered 'I'	System	31 Aug 2020 21:07:44

US3862099

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 11 Jun 2021 15:16:15

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:07:44
	(b) (4)	

US3862099

Folder: Screening

Form: Medical History Summary

Generated On: 11 Jun 2021 15:16:15

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:07:48
	(b) (4)	

US3862099

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:16:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Retroviral infections, PT: HIV infection, LLT: HIV infection - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 21:22:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 21:22:40
Data point term sent to Coder	System	31 Aug 2020 21:21:57
User entered 'HIV'	Carrie Kibler (b) (4)	31 Aug 2020 21:21:40

US3862099

Folder: Screening

Form: Medical History (1)

Generated On: 11 Jun 2021 15:16:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'un Dec 2018'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:21:40
	(b) (4)	

**US3862099**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:21:40

**US3862099**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:21:40
	(b) (4)	

**US3862099**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Jun 2021 15:16:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:21:40
	(b) (4)	

**US3862099**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:21:40

**US3862099**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered 'Dec 2018'	System	31 Aug 2020 21:21:40

**US3862099**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered '2018'	System	31 Aug 2020 21:21:40

**US3862099**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered empty.	System	31 Aug 2020 21:21:40

**US3862099**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered empty.	System	31 Aug 2020 21:21:40

US3862099

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:16:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Hepatitis viral infections, PT: Chronic hepatitis B, LLT: Chronic hepatitis B - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 21:24:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 21:24:04
Data point term sent to Coder	System	31 Aug 2020 21:23:00
User entered 'chronic hepatitis b'	Carrie Kibler (b) (4)	31 Aug 2020 21:22:00

US3862099

Folder: Screening

Form: Medical History (2)

Generated On: 11 Jun 2021 15:16:15

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'un Feb 2005'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:22:00
	(b) (4)	

**US3862099**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '0'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:22:00

**US3862099**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:22:00
	(b) (4)	

**US3862099**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Jun 2021 15:16:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:22:00
	(b) (4)	

**US3862099**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '0'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:22:00
	(b) (4)	

**US3862099**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered 'Feb 2005'	System	31 Aug 2020 21:22:00

**US3862099**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered '2005'	System	31 Aug 2020 21:22:00

**US3862099**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered empty.	System	31 Aug 2020 21:22:00

**US3862099**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered empty.	System	31 Aug 2020 21:22:00

US3862099

Folder: Screening

Form: Medical History (3)

Generated On: 11 Jun 2021 15:16:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Glucose tolerance impaired, LLT: Prediabetes - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 21:23:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	31 Aug 2020 21:23:41
Data point term sent to Coder	System	31 Aug 2020 21:22:59
User entered 'prediabetes'	Carrie Kibler (b) (4)	31 Aug 2020 21:22:12

**US3862099**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'un UNK 2019'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:22:12

**US3862099**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '0'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:22:12
	(b) (4)	

**US3862099**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:22:12
	(b) (4)	

**US3862099**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Jun 2021 15:16:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:22:12

**US3862099**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:22:12

**US3862099**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered 'Jan 2019'	System	31 Aug 2020 21:22:12

**US3862099**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered '2019'	System	31 Aug 2020 21:22:12

**US3862099**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered empty.	System	31 Aug 2020 21:22:12

**US3862099**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered empty.	System	31 Aug 2020 21:22:12

US3862099

Folder: Screening

Form: Medical History (4)

Generated On: 11 Jun 2021 15:16:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:27
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	19 Mar 2021 16:11:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Mar 2021 16:11:33
Data point term sent to Coder	System	19 Mar 2021 16:10:36
User entered 'general body aches'	(b) (4), (b) (6)	19 Mar 2021 16:10:16

**US3862099**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:27
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:10:16

**US3862099**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:27
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:10:16

**US3862099**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:10:16

**US3862099**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Jun 2021 15:16:15**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:27
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:10:16

**US3862099**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 15:56:27
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:10:16

**US3862099**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered 'Jan 2000'	System	19 Mar 2021 16:10:16

**US3862099**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered '2000'	System	19 Mar 2021 16:10:16

**US3862099**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered empty.	System	19 Mar 2021 16:10:16

**US3862099**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered empty.	System	19 Mar 2021 16:10:16

US3862099

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:08:24
	(b) (4)	

US3862099

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '31 Aug 2020'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:08:24
	(b) (4)	

US3862099

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '14:41'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:08:24
	(b) (4)	

**US3862099**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:16:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered '31 Aug 2020 14:41'	System	31 Aug 2020 21:08:24

US3862099

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '73.5' in	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:08:24
DataPoint set to visible.	(b) (4) System	31 Aug 2020 21:07:44

US3862099

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '254' lb	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:08:24
DataPoint set to visible.	(b) (4) System	31 Aug 2020 21:07:44

**US3862099**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:16:15**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered '33.12599'	System	31 Aug 2020 21:08:24
DataPoint set to visible.	System	31 Aug 2020 21:07:44

**US3862099**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:16:15**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered 'kg/m2'	System	31 Aug 2020 21:08:24
DataPoint set to visible.	System	31 Aug 2020 21:07:44

US3862099

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '98.6' F	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:08:24
	(b) (4)	

US3862099

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Other (Other)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:08:24
	(b) (4)	

US3862099

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'temporal'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:08:24
	(b) (4)	

US3862099

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '72'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:08:24
	(b) (4)	

**US3862099**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:16:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered 'bpm'	System	31 Aug 2020 21:08:24

US3862099

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '14'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:08:24
	(b) (4)	

US3862099

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered 'breaths/min'	System	31 Aug 2020 21:08:24

US3862099

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '122'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:08:24
	(b) (4)	

**US3862099**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:16:15**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered 'mmHg'	System	31 Aug 2020 21:08:24

US3862099

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '80'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:08:24

US3862099

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User entered 'mmHg'	System	31 Aug 2020 21:08:24

US3862099

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01

US3862099

Folder: Screening

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01

US3862099

Folder: Screening

Form: Physical Examination

Generated On: 11 Jun 2021 15:16:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:08:29
	(b) (4)	

US3862099

Folder: Screening

Form: Physical Examination

Generated On: 11 Jun 2021 15:16:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '31 Aug 2020'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:08:29
	(b) (4)	

US3862099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:16:15

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:09:20

US3862099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:16:15

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:09:20

US3862099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:16:15

**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)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:09:20
	(b) (4)	

US3862099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:16:15

**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)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:09:20
	(b) (4)	

US3862099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:16:15

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:09:20
	(b) (4)	

US3862099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:16:15

[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)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:09:20
	(b) (4)	

US3862099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:16:15

**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)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:09:20

US3862099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:16:15

[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)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:09:20
	(b) (4)	

US3862099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:16:15

[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)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:09:20
	(b) (4)	

US3862099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:16:15

**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)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:09:20
	(b) (4)	

US3862099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:16:15

**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)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:09:20

US3862099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:16:15

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:09:20
	(b) (4)	

US3862099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:16:15

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:09:20
	(b) (4)	

US3862099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:16:15

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '0'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:09:20
	(b) (4)	

US3862099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:16:15

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '0'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:09:20

US3862099

Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:16:15

**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)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '0'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:09:20
	(b) (4)	

US3862099

Folder: Screening

Form: Risk of Exposure

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[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)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '0'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:09:20

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Folder: Screening

Form: Risk of Exposure

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '0'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:09:20
	(b) (4)	

US3862099

Folder: Screening

Form: Risk of Exposure

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[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'I'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:09:20

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Folder: Screening

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '0'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:09:20
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 11 Jun 2021 15:16:15

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:01
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:09:20
	(b) (4)	

**US3862099**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Jun 2021 15:16:15**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:09:29

**US3862099**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Jun 2021 15:16:15**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '31 Aug 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:09:29

US3862099

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 11 Jun 2021 15:16:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:09:29

**US3862099**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 11 Jun 2021 15:16:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'VISIT1'	System	31 Aug 2020 21:09:29

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '31 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 20:59:32

US3862099

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:16:15

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '145529'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Aug 2020 20:59:32

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:16:15

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
	(b) (4)	
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	21 Sep 2020 21:52:07
Comment added 'Subject is HIV positive which put him at risk for complications per CDC'.	Chanei Henry (b) (4)	09 Sep 2020 21:45:21
	(b) (4)	
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	31 Aug 2020 21:09:46
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	31 Aug 2020 20:59:32
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:16:15

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)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:09:46

US3862099

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:16:15

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)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:09:46

US3862099

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:16:15

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:09:46

US3862099

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:16:15

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:09:46

US3862099

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:16:15

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
	(b) (4)	
User entered 'Yes (Y)' reason for change: Per Query Resolution	Chanei Henry (b) (4)	21 Sep 2020 21:52:07
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	31 Aug 2020 21:09:46
	(b) (4)	

US3862099

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 11 Jun 2021 15:16:15

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	21 Sep 2020 21:52:07
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 08:49:51
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:49:49

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:16:15

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User closed query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:35:20
Query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you.	Trent Davis (b) (4) (b) (4)	02 Nov 2020 17:00:30
' answered with 'data corrected' (Site from DM). User entered missing code ND - Not Done; reason for change Data Entry Error	Trent Davis (b) (4) (b) (4)	02 Nov 2020 17:00:23
User opened query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 09:26:13
User entered '73.5' in	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:10:20

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:16:15

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Nov 2020 17:00:23
User entered '254' lb	Trent Davis (b) (4)	31 Aug 2020 21:10:20
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:16:15

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User closed query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:35:20
Query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you.	Trent Davis (b) (4) (b) (4)	02 Nov 2020 17:00:30
' answered with 'data corrected' (Site from DM). User entered missing code ND - Not Done; reason for change Data Entry Error	Trent Davis (b) (4) (b) (4)	02 Nov 2020 17:00:23
User opened query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 09:26:13
User entered '73.5' in	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:10:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:16:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Nov 2020 17:00:23
User entered '254' lb	Trent Davis (b) (4)	31 Aug 2020 21:10:20
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User accepted default value 'Pre-Dose (PREDOSE)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:10:20

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:10:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '31 Aug 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:10:20

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '14:41'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:10:20

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered '31 Aug 2020 14:41'	System	31 Aug 2020 21:10:20

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '98.6' F	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:10:20
	(b) (4)	

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Other (Other)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:10:20

**US3862099**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Jun 2021 15:16:15**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'temporal'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:10:20

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '72'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:10:20

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'bpm'	System	31 Aug 2020 21:10:20

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '14'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:10:20

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'breaths/min'	System	31 Aug 2020 21:10:20

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '122'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:10:20

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'mmHg'	System	31 Aug 2020 21:10:20

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '80'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:10:20

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'mmHg'	System	31 Aug 2020 21:10:20

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:16:15

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User closed query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Nov 2020 16:35:20
Query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you.	Trent Davis (b) (4) (b) (4)	02 Nov 2020 17:00:30
' answered with 'data corrected' (Site from DM). User entered missing code ND - Not Done; reason for change Data Entry Error	Trent Davis (b) (4) (b) (4)	02 Nov 2020 17:00:23
User opened query 'Per CDM: Patient noted as Screened and Dosed on the same day. Per page 23 of CCGs version 2.0, please record Height and Weight as "ND (Not Done)". Thank you. ' (Site from DM).	(b) (4), (b) (6)	30 Oct 2020 09:26:13
User entered '73.5' in	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:10:20

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:16:15

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	02 Nov 2020 17:00:23
User entered '254' lb	Trent Davis (b) (4)	31 Aug 2020 21:10:20
	(b) (4)	

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User accepted default value 'Post-Dose (POSTDOSE)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:00:59

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:00:59

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '31 Aug 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:00:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '16:53'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:00:59

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered '31 Aug 2020 16:53'	System	31 Aug 2020 22:00:59

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '97.8' F	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:00:59

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Other (Other)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:00:59

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'temporal'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:00:59

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '74'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:00:59

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'bpm'	System	31 Aug 2020 22:00:59

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '18'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:00:59

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'breaths/min'	System	31 Aug 2020 22:00:59

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '118'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:00:59

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'mmHg'	System	31 Aug 2020 22:00:59

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '69'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 22:00:59

US3862099

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'mmHg'	System	31 Aug 2020 22:00:59

US3862099

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Jun 2021 15:16:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:10:29

US3862099

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 11 Jun 2021 15:16:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '31 Aug 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:10:29

US3862099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:27:38

US3862099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:27:38

US3862099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:27:38
	(b) (4)	

US3862099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User entered 'MRNA-1273 OR PLACEBO'	System	31 Aug 2020 21:27:38

US3862099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '31 Aug 2020'	(b) (4) Carrie Kibler (b) (4)	31 Aug 2020 21:27:38
	(b) (4)	

US3862099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '16:23'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:27:38

US3862099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User entered '31 Aug 2020 16:23'	System	31 Aug 2020 21:27:38

US3862099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Left Arm (LEFT ARM)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:27:38

US3862099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User entered 'ONCE'	System	31 Aug 2020 21:27:38

US3862099

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User entered 'INTRAMUSCULAR'	System	31 Aug 2020 21:27:38

US3862099

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:16:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:10:52

US3862099

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:16:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '31 Aug 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:10:52

US3862099

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:16:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '15:39'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:10:52

US3862099

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:16:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User entered '31 Aug 2020 15:39'	System	31 Aug 2020 21:10:52

US3862099

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 11 Jun 2021 15:16:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '31 Aug 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:11:09

US3862099

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:16:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:11:09

US3862099

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:16:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:11:09

US3862099

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 11 Jun 2021 15:16:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '15:15'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:11:09

**US3862099**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User entered '31 Aug 2020 15:15'	System	31 Aug 2020 21:11:09

US3862099

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:16:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:11:12

US3862099

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:16:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:11:12

**US3862099**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:11:12

**US3862099**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User entered empty.	System	31 Aug 2020 21:11:12

US3862099

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 11 Jun 2021 15:16:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:11:14

**US3862099**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:16:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User entered 'I'	System	31 Aug 2020 21:11:14

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T16:54:45', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '272b21b5-f016-4e50-8088-2b20d5e45638' User entered 'Yes (Y)'	System	31 Aug 2020 21:55:28
	System	31 Aug 2020 21:55:28

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T16:55:11', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '272b21b5-f016-4e50-8088-2b20d5e45638' User entered '97.8'	System	31 Aug 2020 21:55:28
	System	31 Aug 2020 21:55:28

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T16:55:18', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '272b21b5-f016-4e50-8088-2b20d5e45638' User entered 'No (N)'	System	31 Aug 2020 21:55:28
	System	31 Aug 2020 21:55:28

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T16:55:21', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '272b21b5-f016-4e50-8088-2b20d5e45638'	System	31 Aug 2020 21:55:28
User entered '31 Aug 2020 16:55'	System	31 Aug 2020 21:55:28

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '31 Aug 2020 16:43'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '31 Aug 2020 19:13'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T21:42:38', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '39e7366d-3025-494b-ba79-08196c70b94f' User entered 'Yes (Y)'	System	01 Sep 2020 02:43:11
	System	01 Sep 2020 02:43:11

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T21:42:45', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '39e7366d-3025-494b-ba79-08196c70b94f' User entered '98.8'	System	01 Sep 2020 02:43:11
	System	01 Sep 2020 02:43:11

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T21:42:52', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '39e7366d-3025-494b-ba79-08196c70b94f' User entered 'No (N)'	System	01 Sep 2020 02:43:11
	System	01 Sep 2020 02:43:11

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T21:42:57', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '39e7366d-3025-494b-ba79-08196c70b94f' User entered '31 Aug 2020 21:42'	System	01 Sep 2020 02:43:11
	System	01 Sep 2020 02:43:11

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '31 Aug 2020 20:08'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 2'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:16:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-01T21:42:11', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'f513a317-1db9-41b6-bb54-4da0d018fd29'	System	02 Sep 2020 02:42:35
User entered 'Yes (Y)'	System	02 Sep 2020 02:42:35

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:16:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-01T21:42:20', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'f513a317-1db9-41b6-bb54-4da0d018fd29' User entered '97.8'	System	02 Sep 2020 02:42:35
	System	02 Sep 2020 02:42:35

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-01T21:42:26', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'f513a317-1db9-41b6-bb54-4da0d018fd29'	System	02 Sep 2020 02:42:35
User entered 'No (N)'	System	02 Sep 2020 02:42:35

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-01T21:42:32', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'f513a317-1db9-41b6-bb54-4da0d018fd29'	System	02 Sep 2020 02:42:35
User entered '01 Sep 2020 21:42'	System	02 Sep 2020 02:42:35

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 3'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:16:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T09:03:08', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '1d25c0d3-834a-4a7e-ac0e-857512ec1603' User entered 'Yes (Y)'	System	03 Sep 2020 14:03:31
	System	03 Sep 2020 14:03:31

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:16:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T09:03:15', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '1d25c0d3-834a-4a7e-ac0e-857512ec1603' User entered '97.9'	System	03 Sep 2020 14:03:31
	System	03 Sep 2020 14:03:31

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T09:03:22', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '1d25c0d3-834a-4a7e-ac0e-857512ec1603'	System	03 Sep 2020 14:03:31
User entered 'No (N)'	System	03 Sep 2020 14:03:31

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T09:03:26', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '1d25c0d3-834a-4a7e-ac0e-857512ec1603' User entered '03 Sep 2020 09:03'	System	03 Sep 2020 14:03:31
	System	03 Sep 2020 14:03:31

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 4'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:16:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T19:02:50', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'c0f71e45-4820-4e72-a722-a100956c5a15' User entered 'Yes (Y)'	System	04 Sep 2020 00:03:11
	System	04 Sep 2020 00:03:11

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:16:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T19:02:57', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'c0f71e45-4820-4e72-a722-a100956c5a15' User entered '97.8'	System	04 Sep 2020 00:03:11
	System	04 Sep 2020 00:03:11

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T19:03:01', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'c0f71e45-4820-4e72-a722-a100956c5a15'	System	04 Sep 2020 00:03:11
User entered 'No (N)'	System	04 Sep 2020 00:03:11

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T19:03:04', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'c0f71e45-4820-4e72-a722-a100956c5a15' User entered '03 Sep 2020 19:03'	System	04 Sep 2020 00:03:11
	System	04 Sep 2020 00:03:11

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 5'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:16:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-04T22:32:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e8e008f8-6937-48d6-8224-98b810ae2110' User entered 'Yes (Y)'	System	05 Sep 2020 03:32:21
	System	05 Sep 2020 03:32:21

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:16:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-04T22:32:06', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e8e008f8-6937-48d6-8224-98b810ae2110' User entered '97.8'	System	05 Sep 2020 03:32:21
	System	05 Sep 2020 03:32:21

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-04T22:32:13', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e8e008f8-6937-48d6-8224-98b810ae2110' User entered 'No (N)'	System	05 Sep 2020 03:32:21
	System	05 Sep 2020 03:32:21

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-04T22:32:17', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e8e008f8-6937-48d6-8224-98b810ae2110' User entered '04 Sep 2020 22:32'	System	05 Sep 2020 03:32:21
	System	05 Sep 2020 03:32:21

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 6'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:16:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-05T12:26:26', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'f1b505de-7cb4-44f5-9027-8947874e3cd0'	System	05 Sep 2020 17:26:47
User entered 'Yes (Y)'	System	05 Sep 2020 17:26:47

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:16:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-05T12:26:32', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'f1b505de-7cb4-44f5-9027-8947874e3cd0' User entered '97.8'	System	05 Sep 2020 17:26:47
	System	05 Sep 2020 17:26:47

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-05T12:26:39', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'f1b505de-7cb4-44f5-9027-8947874e3cd0'	System	05 Sep 2020 17:26:47
User entered 'No (N)'	System	05 Sep 2020 17:26:47

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-05T12:26:43', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'f1b505de-7cb4-44f5-9027-8947874e3cd0' User entered '05 Sep 2020 12:26'	System	05 Sep 2020 17:26:47
	System	05 Sep 2020 17:26:47

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 7'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:16:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:16:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:16:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T16:55:31', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'a25ac94e-0270-493a-b248-4fd69f331a70' User entered 'None (1)'	System	31 Aug 2020 21:55:50
	System	31 Aug 2020 21:55:50

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T16:55:34', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'a25ac94e-0270-493a-b248-4fd69f331a70' User entered 'No (N)'	System	31 Aug 2020 21:55:50
	System	31 Aug 2020 21:55:50

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T16:55:38', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'a25ac94e-0270-493a-b248-4fd69f331a70' User entered 'No (N)'	System	31 Aug 2020 21:55:50
	System	31 Aug 2020 21:55:50

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T16:55:44', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'a25ac94e-0270-493a-b248-4fd69f331a70' User entered 'None (1)'	System	31 Aug 2020 21:55:50
	System	31 Aug 2020 21:55:50

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T16:55:47', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'a25ac94e-0270-493a-b248-4fd69f331a70' User entered '31 Aug 2020 16:55'	System	31 Aug 2020 21:55:50
	System	31 Aug 2020 21:55:50

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '31 Aug 2020 16:43'	System	31 Aug 2020 21:27:38

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '31 Aug 2020 19:13'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T21:43:15', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '266a9e41-b8ee-47e1-8c41-5bf3c27f7af0' User entered 'None (1)'	System	01 Sep 2020 02:44:02
	System	01 Sep 2020 02:44:02

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T21:43:39', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '266a9e41-b8ee-47e1-8c41-5bf3c27f7af0' User entered 'No (N)'	System	01 Sep 2020 02:44:02
	System	01 Sep 2020 02:44:02

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T21:43:45', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '266a9e41-b8ee-47e1-8c41-5bf3c27f7af0' User entered 'No (N)'	System	01 Sep 2020 02:44:02
	System	01 Sep 2020 02:44:02

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T21:43:56', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '266a9e41-b8ee-47e1-8c41-5bf3c27f7af0' User entered 'None (1)'	System	01 Sep 2020 02:44:02
	System	01 Sep 2020 02:44:02

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T21:44:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '266a9e41-b8ee-47e1-8c41-5bf3c27f7af0' User entered '31 Aug 2020 21:44'	System	01 Sep 2020 02:44:02
	System	01 Sep 2020 02:44:02

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '31 Aug 2020 20:08'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 2'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-01T21:42:37', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '60c94a39-f0a4-4351-9266-84a6ae461480' User entered 'None (1)'	System	02 Sep 2020 02:42:53
	System	02 Sep 2020 02:42:53

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:16:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-01T21:42:40', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '60c94a39-f0a4-4351-9266-84a6ae461480' User entered 'No (N)'	System	02 Sep 2020 02:42:53
	System	02 Sep 2020 02:42:53

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-01T21:42:43', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '60c94a39-f0a4-4351-9266-84a6ae461480' User entered 'No (N)'	System	02 Sep 2020 02:42:53
	System	02 Sep 2020 02:42:53

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-01T21:42:46', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '60c94a39-f0a4-4351-9266-84a6ae461480' User entered 'None (1)'	System	02 Sep 2020 02:42:53
	System	02 Sep 2020 02:42:53

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-01T21:42:49', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '60c94a39-f0a4-4351-9266-84a6ae461480' User entered '01 Sep 2020 21:42'	System	02 Sep 2020 02:42:53
	System	02 Sep 2020 02:42:53

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 21:27:38

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 3'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T09:03:32', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '7f0278f4-acce-49e2-9b06-2363cad6a086'	System	03 Sep 2020 14:03:55
User entered 'None (1)'	System	03 Sep 2020 14:03:55

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:16:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T09:03:38', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '7f0278f4-acce-49e2-9b06-2363cad6a086'	System	03 Sep 2020 14:03:55
User entered 'No (N)'	System	03 Sep 2020 14:03:55

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T09:03:42', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '7f0278f4-acce-49e2-9b06-2363cad6a086'	System	03 Sep 2020 14:03:55
User entered 'No (N)'	System	03 Sep 2020 14:03:55

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T09:03:47', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '7f0278f4-acce-49e2-9b06-2363cad6a086'	System	03 Sep 2020 14:03:55
User entered 'None (1)'	System	03 Sep 2020 14:03:55

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T09:03:51', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '7f0278f4-acce-49e2-9b06-2363cad6a086' User entered '03 Sep 2020 09:03'	System	03 Sep 2020 14:03:55
	System	03 Sep 2020 14:03:55

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 21:27:38

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 4'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T19:03:16', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'a406e5a3-d15a-4a68-aa16-14c8d65d5ff5'	System	04 Sep 2020 00:03:33
User entered 'None (1)'	System	04 Sep 2020 00:03:33

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:16:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T19:03:20', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'a406e5a3-d15a-4a68-aa16-14c8d65d5ff5'	System	04 Sep 2020 00:03:33
User entered 'No (N)'	System	04 Sep 2020 00:03:33

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T19:03:24', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'a406e5a3-d15a-4a68-aa16-14c8d65d5ff5'	System	04 Sep 2020 00:03:33
User entered 'No (N)'	System	04 Sep 2020 00:03:33

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T19:03:27', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'a406e5a3-d15a-4a68-aa16-14c8d65d5ff5'	System	04 Sep 2020 00:03:33
User entered 'None (1)'	System	04 Sep 2020 00:03:33

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T19:03:31', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'a406e5a3-d15a-4a68-aa16-14c8d65d5ff5'	System	04 Sep 2020 00:03:33
User entered '03 Sep 2020 19:03'	System	04 Sep 2020 00:03:33

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 5'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-04T22:32:22', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '5355c3fa-d4f3-4435-8b0b-4dd67009f946'	System	05 Sep 2020 03:32:39
User entered 'None (1)'	System	05 Sep 2020 03:32:39

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:16:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-04T22:32:25', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '5355c3fa-d4f3-4435-8b0b-4dd67009f946' User entered 'No (N)'	System	05 Sep 2020 03:32:39
	System	05 Sep 2020 03:32:39

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-04T22:32:30', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '5355c3fa-d4f3-4435-8b0b-4dd67009f946' User entered 'No (N)'	System	05 Sep 2020 03:32:39
	System	05 Sep 2020 03:32:39

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-04T22:32:33', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '5355c3fa-d4f3-4435-8b0b-4dd67009f946'	System	05 Sep 2020 03:32:39
User entered 'None (1)'	System	05 Sep 2020 03:32:39

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-04T22:32:37', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '5355c3fa-d4f3-4435-8b0b-4dd67009f946'	System	05 Sep 2020 03:32:39
User entered '04 Sep 2020 22:32'	System	05 Sep 2020 03:32:39

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 6'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-05T12:26:54', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '6792e6e9-345d-4d3c-bb1d-36b6c59b5724'	System	05 Sep 2020 17:27:06
User entered 'None (1)'	System	05 Sep 2020 17:27:06

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:16:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-05T12:26:56', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '6792e6e9-345d-4d3c-bb1d-36b6c59b5724' User entered 'No (N)'	System	05 Sep 2020 17:27:06
	System	05 Sep 2020 17:27:06

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-05T12:26:58', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '6792e6e9-345d-4d3c-bb1d-36b6c59b5724' User entered 'No (N)'	System	05 Sep 2020 17:27:06
	System	05 Sep 2020 17:27:06

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-05T12:27:01', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '6792e6e9-345d-4d3c-bb1d-36b6c59b5724'	System	05 Sep 2020 17:27:06
User entered 'None (1)'	System	05 Sep 2020 17:27:06

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-05T12:27:04', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '6792e6e9-345d-4d3c-bb1d-36b6c59b5724' User entered '05 Sep 2020 12:27'	System	05 Sep 2020 17:27:06
	System	05 Sep 2020 17:27:06

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 21:27:38

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 7'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:16:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:16:15

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:16:15

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Aug 2020 21:27:38

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Jun 2021 15:16:15**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T16:55:53', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '067fa4eb-039e-4384-980e-35a017837c86' User entered 'None (0)'	System	31 Aug 2020 21:56:19
	System	31 Aug 2020 21:56:19

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T16:55:56', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '067fa4eb-039e-4384-980e-35a017837c86' User entered 'None (0)'	System	31 Aug 2020 21:56:19
	System	31 Aug 2020 21:56:19

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T16:56:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '067fa4eb-039e-4384-980e-35a017837c86' User entered 'None (0)'	System	31 Aug 2020 21:56:19
	System	31 Aug 2020 21:56:19

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T16:56:03', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '067fa4eb-039e-4384-980e-35a017837c86' User entered 'None (0)'	System	31 Aug 2020 21:56:19
	System	31 Aug 2020 21:56:19

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T16:56:05', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '067fa4eb-039e-4384-980e-35a017837c86' User entered 'None (0)'	System	31 Aug 2020 21:56:19
	System	31 Aug 2020 21:56:19

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T16:56:07', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '067fa4eb-039e-4384-980e-35a017837c86' User entered 'None (0)'	System	31 Aug 2020 21:56:19
	System	31 Aug 2020 21:56:19

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

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)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T16:56:15', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '067fa4eb-039e-4384-980e-35a017837c86' User entered 'No (N)'	System	31 Aug 2020 21:56:19
	System	31 Aug 2020 21:56:19

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T16:56:17', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '067fa4eb-039e-4384-980e-35a017837c86' User entered '31 Aug 2020 16:56'	System	31 Aug 2020 21:56:19
	System	31 Aug 2020 21:56:19

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '31 Aug 2020 16:43'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '31 Aug 2020 19:13'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 1, after vaccination (at home)'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T21:44:32', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '68a845d6-d7e2-4f8b-85d2-c3c8552eda68'	System	01 Sep 2020 02:45:07
User entered 'No interference with activity (1)'	System	01 Sep 2020 02:45:07

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T21:44:36', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '68a845d6-d7e2-4f8b-85d2-c3c8552eda68' User entered 'None (0)'	System	01 Sep 2020 02:45:07
	System	01 Sep 2020 02:45:07

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T21:44:43', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '68a845d6-d7e2-4f8b-85d2-c3c8552eda68' User entered 'No interference with activity (1)'	System	01 Sep 2020 02:45:07
	System	01 Sep 2020 02:45:07

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T21:44:48', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '68a845d6-d7e2-4f8b-85d2-c3c8552eda68'	System	01 Sep 2020 02:45:07
User entered 'No interference with activity (1)'	System	01 Sep 2020 02:45:07

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T21:44:52', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '68a845d6-d7e2-4f8b-85d2-c3c8552eda68' User entered 'None (0)'	System	01 Sep 2020 02:45:07
	System	01 Sep 2020 02:45:07

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T21:44:54', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '68a845d6-d7e2-4f8b-85d2-c3c8552eda68' User entered 'None (0)'	System	01 Sep 2020 02:45:07
	System	01 Sep 2020 02:45:07

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

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)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T21:45:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '68a845d6-d7e2-4f8b-85d2-c3c8552eda68' User entered 'No (N)'	System	01 Sep 2020 02:45:07
	System	01 Sep 2020 02:45:07

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-08-31T21:45:04', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '68a845d6-d7e2-4f8b-85d2-c3c8552eda68' User entered '31 Aug 2020 21:45'	System	01 Sep 2020 02:45:07
	System	01 Sep 2020 02:45:07

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '31 Aug 2020 20:08'	System	31 Aug 2020 21:27:38

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '01 Sep 2020 11:59'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 2'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-01T21:42:56', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '90d0121d-64d6-4fed-8207-ef1af55a6cf6' User entered 'None (0)'	System	02 Sep 2020 02:43:20
	System	02 Sep 2020 02:43:20

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-01T21:42:58', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '90d0121d-64d6-4fed-8207-ef1af55a6cf6' User entered 'None (0)'	System	02 Sep 2020 02:43:20
	System	02 Sep 2020 02:43:20

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-01T21:43:01', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '90d0121d-64d6-4fed-8207-ef1af55a6cf6' User entered 'None (0)'	System	02 Sep 2020 02:43:20
	System	02 Sep 2020 02:43:20

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-01T21:43:05', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '90d0121d-64d6-4fed-8207-ef1af55a6cf6' User entered 'None (0)'	System	02 Sep 2020 02:43:20
	System	02 Sep 2020 02:43:20

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-01T21:43:07', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '90d0121d-64d6-4fed-8207-ef1af55a6cf6' User entered 'None (0)'	System	02 Sep 2020 02:43:20
	System	02 Sep 2020 02:43:20

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-01T21:43:09', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '90d0121d-64d6-4fed-8207-ef1af55a6cf6' User entered 'None (0)'	System	02 Sep 2020 02:43:20
	System	02 Sep 2020 02:43:20

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

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)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-01T21:43:16', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '90d0121d-64d6-4fed-8207-ef1af55a6cf6' User entered 'No (N)'	System	02 Sep 2020 02:43:20
	System	02 Sep 2020 02:43:20

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-01T21:43:18', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '90d0121d-64d6-4fed-8207-ef1af55a6cf6' User entered '01 Sep 2020 21:43'	System	02 Sep 2020 02:43:20
	System	02 Sep 2020 02:43:20

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '01 Sep 2020 12:00'	System	31 Aug 2020 21:27:38

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '02 Sep 2020 11:59'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 3'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T09:03:56', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '4179ccc9-10bf-4d3a-96c3-40d75940acc2' User entered 'None (0)'	System	03 Sep 2020 14:04:28
	System	03 Sep 2020 14:04:28

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T09:03:59', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '4179ccc9-10bf-4d3a-96c3-40d75940acc2' User entered 'None (0)'	System	03 Sep 2020 14:04:28
	System	03 Sep 2020 14:04:28

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T09:04:04', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '4179ccc9-10bf-4d3a-96c3-40d75940acc2' User entered 'None (0)'	System	03 Sep 2020 14:04:28
	System	03 Sep 2020 14:04:28

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T09:04:11', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '4179ccc9-10bf-4d3a-96c3-40d75940acc2' User entered 'None (0)'	System	03 Sep 2020 14:04:28
	System	03 Sep 2020 14:04:28

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T09:04:15', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '4179ccc9-10bf-4d3a-96c3-40d75940acc2' User entered 'None (0)'	System	03 Sep 2020 14:04:28
	System	03 Sep 2020 14:04:28

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T09:04:17', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '4179ccc9-10bf-4d3a-96c3-40d75940acc2' User entered 'None (0)'	System	03 Sep 2020 14:04:28
	System	03 Sep 2020 14:04:28

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

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)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T09:04:23', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '4179ccc9-10bf-4d3a-96c3-40d75940acc2' User entered 'No (N)'	System	03 Sep 2020 14:04:28
	System	03 Sep 2020 14:04:28

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T09:04:27', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '4179ccc9-10bf-4d3a-96c3-40d75940acc2' User entered '03 Sep 2020 09:04'	System	03 Sep 2020 14:04:28
	System	03 Sep 2020 14:04:28

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '02 Sep 2020 12:00'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '03 Sep 2020 11:59'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 4'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T19:03:35', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '6beb2882-3684-45c7-9a7b-2b901e371e95' User entered 'None (0)'	System	04 Sep 2020 00:03:57
	System	04 Sep 2020 00:03:57

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T19:03:38', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '6beb2882-3684-45c7-9a7b-2b901e371e95' User entered 'None (0)'	System	04 Sep 2020 00:03:57
	System	04 Sep 2020 00:03:57

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T19:03:40', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '6beb2882-3684-45c7-9a7b-2b901e371e95' User entered 'None (0)'	System	04 Sep 2020 00:03:57
	System	04 Sep 2020 00:03:57

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T19:03:43', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '6beb2882-3684-45c7-9a7b-2b901e371e95' User entered 'None (0)'	System	04 Sep 2020 00:03:57
	System	04 Sep 2020 00:03:57

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T19:03:46', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '6beb2882-3684-45c7-9a7b-2b901e371e95' User entered 'None (0)'	System	04 Sep 2020 00:03:57
	System	04 Sep 2020 00:03:57

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T19:03:48', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '6beb2882-3684-45c7-9a7b-2b901e371e95' User entered 'None (0)'	System	04 Sep 2020 00:03:57
	System	04 Sep 2020 00:03:57

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:16:15

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)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T19:03:51', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '6beb2882-3684-45c7-9a7b-2b901e371e95'	System	04 Sep 2020 00:03:57
User entered 'No (N)'	System	04 Sep 2020 00:03:57

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:16:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-03T19:03:55', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '6beb2882-3684-45c7-9a7b-2b901e371e95' User entered '03 Sep 2020 19:03'	System	04 Sep 2020 00:03:57
	System	04 Sep 2020 00:03:57

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '03 Sep 2020 12:00'	System	31 Aug 2020 21:27:38

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '04 Sep 2020 11:59'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 5'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-04T22:32:43', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8cf253aa-bff0-408e-be87-5fc956973431' User entered 'None (0)'	System	05 Sep 2020 03:33:06
	System	05 Sep 2020 03:33:06

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-04T22:32:45', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8cf253aa-bff0-408e-be87-5fc956973431' User entered 'None (0)'	System	05 Sep 2020 03:33:06
	System	05 Sep 2020 03:33:06

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-04T22:32:48', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8cf253aa-bff0-408e-be87-5fc956973431' User entered 'None (0)'	System	05 Sep 2020 03:33:06
	System	05 Sep 2020 03:33:06

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-04T22:32:50', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8cf253aa-bff0-408e-be87-5fc956973431' User entered 'None (0)'	System	05 Sep 2020 03:33:06
	System	05 Sep 2020 03:33:06

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-04T22:32:52', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8cf253aa-bff0-408e-be87-5fc956973431' User entered 'None (0)'	System	05 Sep 2020 03:33:06
	System	05 Sep 2020 03:33:06

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-04T22:32:55', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8cf253aa-bff0-408e-be87-5fc956973431' User entered 'None (0)'	System	05 Sep 2020 03:33:06
	System	05 Sep 2020 03:33:06

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

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)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-04T22:33:01', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8cf253aa-bff0-408e-be87-5fc956973431' User entered 'No (N)'	System	05 Sep 2020 03:33:06
	System	05 Sep 2020 03:33:06

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-04T22:33:04', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8cf253aa-bff0-408e-be87-5fc956973431' User entered '04 Sep 2020 22:33'	System	05 Sep 2020 03:33:06
	System	05 Sep 2020 03:33:06

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '04 Sep 2020 12:00'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '05 Sep 2020 11:59'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 6'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-05T12:27:08', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '11f3b0d0-dcc7-47f2-b84f-95f9ac4df586' User entered 'None (0)'	System	05 Sep 2020 17:27:28
	System	05 Sep 2020 17:27:28

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-05T12:27:09', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '11f3b0d0-dcc7-47f2-b84f-95f9ac4df586' User entered 'None (0)'	System	05 Sep 2020 17:27:28
	System	05 Sep 2020 17:27:28

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-05T12:27:12', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '11f3b0d0-dcc7-47f2-b84f-95f9ac4df586' User entered 'None (0)'	System	05 Sep 2020 17:27:28
	System	05 Sep 2020 17:27:28

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-05T12:27:15', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '11f3b0d0-dcc7-47f2-b84f-95f9ac4df586' User entered 'None (0)'	System	05 Sep 2020 17:27:28
	System	05 Sep 2020 17:27:28

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-05T12:27:17', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '11f3b0d0-dcc7-47f2-b84f-95f9ac4df586' User entered 'None (0)'	System	05 Sep 2020 17:27:28
	System	05 Sep 2020 17:27:28

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-05T12:27:18', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '11f3b0d0-dcc7-47f2-b84f-95f9ac4df586' User entered 'None (0)'	System	05 Sep 2020 17:27:28
	System	05 Sep 2020 17:27:28

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

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)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-05T12:27:22', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '11f3b0d0-dcc7-47f2-b84f-95f9ac4df586' User entered 'No (N)'	System	05 Sep 2020 17:27:28
	System	05 Sep 2020 17:27:28

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-05T12:27:24', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '11f3b0d0-dcc7-47f2-b84f-95f9ac4df586' User entered '05 Sep 2020 12:27'	System	05 Sep 2020 17:27:28
	System	05 Sep 2020 17:27:28

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '05 Sep 2020 12:00'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '06 Sep 2020 11:59'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 7'	System	31 Aug 2020 21:27:38

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08

US3862099

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:16:15

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)	05 Mar 2021 00:39:08

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '06 Sep 2020 12:00'	System	31 Aug 2020 21:27:38

**US3862099**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '07 Sep 2020 11:59'	System	31 Aug 2020 21:27:38

**US3862099**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	09 Sep 2020 21:40:56
	(b) (4)	

**US3862099**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '9 Sep 2020'	(b) (4) Chanei Henry (b) (4)	09 Sep 2020 21:40:56
	(b) (4)	

**US3862099**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Chanei Henry (b) (4)	09 Sep 2020 21:40:56

**US3862099**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Chanei Henry (b) (4)	09 Sep 2020 21:40:56
	(b) (4)	

US3862099

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:16:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	09 Sep 2020 21:41:02
	(b) (4)	

**US3862099**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:16:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User entered 'I'	System	09 Sep 2020 21:41:02

**US3862099**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	25 Sep 2020 21:16:58

**US3862099**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '14 Sep 2020'	(b) (4) Sandra Francisco (b) (4)	25 Sep 2020 21:16:58

**US3862099**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sandra Francisco (b) (4)	25 Sep 2020 21:16:58

US3862099

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:16:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Sandra Francisco (b) (4)	25 Sep 2020 21:16:58

US3862099

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:16:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4)	25 Sep 2020 21:17:03

**US3862099**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:16:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User entered 'I'	System	25 Sep 2020 21:17:03

**US3862099**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4)	25 Sep 2020 21:17:12

US3862099

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:16:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User closed query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 06:34:23
Query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'Safety Call Day 22 was completed out of window. A protocol deviation will be filled in source documentation. Please advise if further action is needed.' (Site from System).	Sandra Francisco (b) (4) (b) (4)	25 Sep 2020 21:17:15
User opened query 'Safety Call Day 22 'Date of Contact or Contact Attempt' is less than 21 days or greater than 24 days after Visit 1 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	25 Sep 2020 21:17:12
User entered '25 Sep 2020'	Sandra Francisco (b) (4) (b) (4)	25 Sep 2020 21:17:12

**US3862099**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sandra Francisco (b) (4)	25 Sep 2020 21:17:12

US3862099

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:16:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Sandra Francisco (b) (4)	25 Sep 2020 21:17:12

US3862099

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:16:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:15:45

**US3862099**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:16:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User entered 'I'	System	28 Sep 2020 21:15:45

US3862099

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:16:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:16:40

US3862099

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:16:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '28 Sep 2020'	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:16:40
	(b) (4)	

US3862099

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:16:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Clinic (Clinic)'	Trent Davis (b) (4)	28 Sep 2020 21:16:40

**US3862099**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 11 Jun 2021 15:16:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'VISIT2'	System	28 Sep 2020 21:16:40

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User accepted default value 'Pre-Dose (PREDOSE)'	Trent Davis (b) (4) (b) (4)	28 Sep 2020 21:20:29

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:20:29

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '28 Sep 2020'	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:20:29
	(b) (4)	

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '14:41'	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:20:29

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered '28 Sep 2020 14:41'	System	28 Sep 2020 21:20:29

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '098.4' F	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:20:29

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Oral (Oral)'	(b) (4) Trent Davis (b) (4) (b) (4)	28 Sep 2020 21:20:29

**US3862099**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Jun 2021 15:16:15**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:20:29

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '078'	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:20:29
	(b) (4)	

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'bpm'	System	28 Sep 2020 21:20:29

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '018'	(b) (4) Trent Davis (b) (4) (b) (4)	28 Sep 2020 21:20:29

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'breaths/min'	System	28 Sep 2020 21:20:29

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '114'	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:20:29

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'mmHg'	System	28 Sep 2020 21:20:29

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '070'	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:20:29

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'mmHg'	System	28 Sep 2020 21:20:29

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User accepted default value 'Post-Dose (POSTDOSE)'	Trent Davis (b) (4) (b) (4)	28 Sep 2020 21:20:29

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Oct 2020 19:35:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Oct 2020 19:35:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	26 Oct 2020 19:35:24
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 21:20:29
User entered empty.	Trent Davis (b) (4)	28 Sep 2020 21:20:29
	(b) (4)	

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
	(b) (4)	
User entered '28 Sep 2020' reason for change: Data Entry Error	Shetel Anassi (b) (4)	26 Oct 2020 19:35:24
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	28 Sep 2020 21:20:29
	(b) (4)	

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '16:38' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:35:24
User entered empty.	Shetel Anassi (b) (4)	28 Sep 2020 21:20:29
	(b) (4)	

**US3862099**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered '28 Sep 2020 16:38'	System	26 Oct 2020 19:35:24
User entered empty.	System	28 Sep 2020 21:20:29

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '097.8' F reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:35:24
User entered empty.	Shetel Anassi (b) (4)	28 Sep 2020 21:20:29
	(b) (4)	

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:35:24
User entered empty.	Shetel Anassi (b) (4)	28 Sep 2020 21:20:29
	(b) (4)	

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
	(b) (4)	
User entered 'Temporal' reason for change: Data Entry Error	Shetel Anassi (b) (4)	26 Oct 2020 19:35:24
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	28 Sep 2020 21:20:29
	(b) (4)	

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
	(b) (4)	
User entered '077' reason for change: Data Entry Error	Shetel Anassi (b) (4)	26 Oct 2020 19:35:24
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	28 Sep 2020 21:20:29
	(b) (4)	

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'bpm'	System	26 Oct 2020 19:35:24
User entered empty.	System	28 Sep 2020 21:20:29

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
	(b) (4)	
User entered '018' reason for change: Data Entry Error	Shetel Anassi (b) (4)	26 Oct 2020 19:35:24
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	28 Sep 2020 21:20:29
	(b) (4)	

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'breaths/min'	System	26 Oct 2020 19:35:24
User entered empty.	System	28 Sep 2020 21:20:29

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
	(b) (4)	
User entered '133' reason for change: Data Entry Error	Shetel Anassi (b) (4)	26 Oct 2020 19:35:24
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	28 Sep 2020 21:20:29
	(b) (4)	

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'mmHg'	System	26 Oct 2020 19:35:24
User entered empty.	System	28 Sep 2020 21:20:29

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
	(b) (4)	
User entered '080' reason for change: Data Entry Error	Shetel Anassi (b) (4)	26 Oct 2020 19:35:24
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	28 Sep 2020 21:20:29
	(b) (4)	

US3862099

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'mmHg'	System	26 Oct 2020 19:35:24
User entered empty.	System	28 Sep 2020 21:20:29

US3862099

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:16:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:16:24

US3862099

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:16:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '28 Sep 2020'	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:16:24
	(b) (4)	

US3862099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:16:11

US3862099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:16:11

US3862099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:16:11
	(b) (4)	

US3862099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'MRNA-1273 OR PLACEBO'	System	28 Sep 2020 21:16:11

US3862099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '28 Sep 2020'	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:16:11
	(b) (4)	

US3862099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '16:03'	(b) (4) Trent Davis (b) (4) (b) (4)	28 Sep 2020 21:16:11

US3862099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered '28 Sep 2020 16:03'	System	28 Sep 2020 21:16:11

US3862099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Left Arm (LEFT ARM)'	(b) (4) Trent Davis (b) (4) (b) (4)	28 Sep 2020 21:16:11

US3862099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'ONCE'	System	28 Sep 2020 21:16:11

US3862099

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'INTRAMUSCULAR'	System	28 Sep 2020 21:16:11

US3862099

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:16:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:58:35
	(b) (4)	

US3862099

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:16:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '28 Sep 2020'	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:58:35
	(b) (4)	

US3862099

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:16:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '15:23'	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:58:35
	(b) (4)	

US3862099

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:16:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered '28 Sep 2020 15:23'	System	28 Sep 2020 21:58:35

**US3862099**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 11 Jun 2021 15:16:15**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '28 Sep 2020'	Trent Davis (b) (4)	28 Sep 2020 21:58:48

**US3862099**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Trent Davis (b) (4) (b) (4)	28 Sep 2020 21:58:48

**US3862099**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:58:48

**US3862099**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:58:48

**US3862099**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered empty.	System	28 Sep 2020 21:58:48

**US3862099**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Trent Davis (b) (4) (b) (4)	28 Sep 2020 21:58:48

US3862099

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 11 Jun 2021 15:16:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:58:48

**US3862099**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '15:15'	(b) (4) Trent Davis (b) (4) (b) (4)	28 Sep 2020 21:58:48

**US3862099**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered '28 Sep 2020 15:15'	System	28 Sep 2020 21:58:48

US3862099

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:16:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	28 Sep 2020 21:59:12

**US3862099**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:16:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'I'	System	28 Sep 2020 21:59:12

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-28T18:10:13', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '2a5de1d9-3dd4-47c9-99b8-92265e3a81fe' User entered 'Yes (Y)'	System	28 Sep 2020 23:10:30
	System	28 Sep 2020 23:10:30

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-28T18:10:21', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '2a5de1d9-3dd4-47c9-99b8-92265e3a81fe' User entered '97.5'	System	28 Sep 2020 23:10:30
	System	28 Sep 2020 23:10:30

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-28T18:10:25', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '2a5de1d9-3dd4-47c9-99b8-92265e3a81fe' User entered 'No (N)'	System	28 Sep 2020 23:10:30
	System	28 Sep 2020 23:10:30

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-28T18:10:28', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '2a5de1d9-3dd4-47c9-99b8-92265e3a81fe' User entered '28 Sep 2020 18:10'	System	28 Sep 2020 23:10:30
	System	28 Sep 2020 23:10:30

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '28 Sep 2020 16:23'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '28 Sep 2020 18:53'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T07:56:26', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '21c832c8-5981-4bad-8c75-eff5a994c488' User entered 'Yes (Y)'	System	29 Sep 2020 12:56:44
	System	29 Sep 2020 12:56:44

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T07:56:33', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '21c832c8-5981-4bad-8c75-eff5a994c488' User entered '97.5'	System	29 Sep 2020 12:56:44
	System	29 Sep 2020 12:56:44

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T07:56:37', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '21c832c8-5981-4bad-8c75-eff5a994c488'	System	29 Sep 2020 12:56:44
User entered 'No (N)'	System	29 Sep 2020 12:56:44

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T07:56:42', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '21c832c8-5981-4bad-8c75-eff5a994c488' User entered '29 Sep 2020 07:56'	System	29 Sep 2020 12:56:44
	System	29 Sep 2020 12:56:44

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '28 Sep 2020 19:48'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 2'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:16:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T12:00:37', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8e3797b6-590e-454b-a11e-7b8430d49d39' User entered 'Yes (Y)'	System	29 Sep 2020 17:01:09
	System	29 Sep 2020 17:01:09

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:16:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T12:00:43', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8e3797b6-590e-454b-a11e-7b8430d49d39' User entered '97.5'	System	29 Sep 2020 17:01:09
	System	29 Sep 2020 17:01:09

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T12:00:48', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8e3797b6-590e-454b-a11e-7b8430d49d39'	System	29 Sep 2020 17:01:09
User entered 'No (N)'	System	29 Sep 2020 17:01:09

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T12:00:53', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8e3797b6-590e-454b-a11e-7b8430d49d39' User entered '29 Sep 2020 12:00'	System	29 Sep 2020 17:01:09
	System	29 Sep 2020 17:01:09

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 3'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:16:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-30T23:05:43', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '36252a17-9574-48a2-b2d2-ad66e57775bf' User entered 'Yes (Y)'	System	01 Oct 2020 04:06:01
	System	01 Oct 2020 04:06:01

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:16:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-30T23:05:49', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '36252a17-9574-48a2-b2d2-ad66e57775bf' User entered '97.5'	System	01 Oct 2020 04:06:01
	System	01 Oct 2020 04:06:01

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-30T23:05:54', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '36252a17-9574-48a2-b2d2-ad66e57775bf' User entered 'No (N)'	System	01 Oct 2020 04:06:01
	System	01 Oct 2020 04:06:01

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-30T23:05:57', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '36252a17-9574-48a2-b2d2-ad66e57775bf' User entered '30 Sep 2020 23:05'	System	01 Oct 2020 04:06:01
	System	01 Oct 2020 04:06:01

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 4'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:16:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-01T12:00:39', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'd9e48f77-efa2-4bc8-a7b5-7e7d5f54dbe1' User entered 'Yes (Y)'	System	01 Oct 2020 17:01:40
	System	01 Oct 2020 17:01:40

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:16:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-01T12:00:57', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'd9e48f77-efa2-4bc8-a7b5-7e7d5f54dbe1' User entered '98.0'	System	01 Oct 2020 17:01:40
	System	01 Oct 2020 17:01:40

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-01T12:01:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'd9e48f77-efa2-4bc8-a7b5-7e7d5f54dbe1' User entered 'No (N)'	System	01 Oct 2020 17:01:40
	System	01 Oct 2020 17:01:40

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-01T12:01:06', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'd9e48f77-efa2-4bc8-a7b5-7e7d5f54dbe1' User entered '01 Oct 2020 12:01'	System	01 Oct 2020 17:01:40
	System	01 Oct 2020 17:01:40

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 5'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:16:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-02T12:55:18', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'd3fdc381-6605-4e88-8c1d-b01e6099898b' User entered 'Yes (Y)'	System	02 Oct 2020 17:55:38
	System	02 Oct 2020 17:55:38

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:16:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-02T12:55:24', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'd3fdc381-6605-4e88-8c1d-b01e6099898b' User entered '97.5'	System	02 Oct 2020 17:55:38
	System	02 Oct 2020 17:55:38

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-02T12:55:29', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'd3fdc381-6605-4e88-8c1d-b01e6099898b' User entered 'No (N)'	System	02 Oct 2020 17:55:38
	System	02 Oct 2020 17:55:38

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-02T12:55:33', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'd3fdc381-6605-4e88-8c1d-b01e6099898b' User entered '02 Oct 2020 12:55'	System	02 Oct 2020 17:55:38
	System	02 Oct 2020 17:55:38

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 6'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:16:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-03T18:56:01', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'b3d27d12-2ae1-421a-a7ca-6b39264a6bfb' User entered 'Yes (Y)'	System	03 Oct 2020 23:56:14
	System	03 Oct 2020 23:56:14

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:16:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-03T18:56:07', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'b3d27d12-2ae1-421a-a7ca-6b39264a6bfb' User entered '97.5'	System	03 Oct 2020 23:56:14
	System	03 Oct 2020 23:56:14

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-03T18:56:10', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'b3d27d12-2ae1-421a-a7ca-6b39264a6bfb' User entered 'No (N)'	System	03 Oct 2020 23:56:14
	System	03 Oct 2020 23:56:14

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-03T18:56:13', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'b3d27d12-2ae1-421a-a7ca-6b39264a6bfb' User entered '03 Oct 2020 18:56'	System	03 Oct 2020 23:56:14
	System	03 Oct 2020 23:56:14

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 7'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:16:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-04T12:00:26', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '91a3d7e3-15de-44c5-bea2-8f12d3dcb320'	System	04 Oct 2020 17:00:50
User entered 'Yes (Y)'	System	04 Oct 2020 17:00:50

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:16:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-04T12:00:31', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '91a3d7e3-15de-44c5-bea2-8f12d3dcb320' User entered '97.5'	System	04 Oct 2020 17:00:50
	System	04 Oct 2020 17:00:50

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-04T12:00:33', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '91a3d7e3-15de-44c5-bea2-8f12d3dcb320'	System	04 Oct 2020 17:00:50
User entered 'Yes (Y)'	System	04 Oct 2020 17:00:50

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant Contacted.' (Site from System).	(b) (4)	03 Nov 2020 14:02:50
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Shetel Anassi (b) (4)	26 Oct 2020 16:23:15
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-04T12:00:36', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '91a3d7e3-15de-44c5-bea2-8f12d3dcb320'	System	04 Oct 2020 17:00:50
User entered '1'	System	04 Oct 2020 17:00:50

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:16:15

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User closed query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Participant Contacted.' (Site from System).	(b) (4)	03 Nov 2020 14:02:52
User opened query 'Per the participant response, medication was taken to prevent pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Shetel Anassi (b) (4)	26 Oct 2020 16:23:20
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-04T12:00:36', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '91a3d7e3-15de-44c5-bea2-8f12d3dcb320'	(b) (4)	
User entered '1'	System	04 Oct 2020 17:00:50
	System	04 Oct 2020 17:00:50
	System	04 Oct 2020 17:00:50

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-04T12:00:39', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '91a3d7e3-15de-44c5-bea2-8f12d3dcb320' User entered '04 Oct 2020 12:00'	System	04 Oct 2020 17:00:50
	System	04 Oct 2020 17:00:50

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	04 Oct 2020 17:00:50
User entered 'Day 8'	System	04 Oct 2020 17:00:50

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 11 Jun 2021 15:16:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-06T07:08:26', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'c041ad50-c724-44e9-9090-92a14ed78cb2' User entered 'Yes (Y)'	System	06 Oct 2020 12:08:50
	System	06 Oct 2020 12:08:50

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 11 Jun 2021 15:16:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-06T07:08:33', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'c041ad50-c724-44e9-9090-92a14ed78cb2' User entered '97.5'	System	06 Oct 2020 12:08:50
	System	06 Oct 2020 12:08:50

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-06T07:08:35', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'c041ad50-c724-44e9-9090-92a14ed78cb2' User entered 'No (N)'	System	06 Oct 2020 12:08:50
	System	06 Oct 2020 12:08:50

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-06T07:08:38', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'c041ad50-c724-44e9-9090-92a14ed78cb2' User entered '06 Oct 2020 07:08'	System	06 Oct 2020 12:08:50
	System	06 Oct 2020 12:08:50

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 17:00:50

US3862099

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(8)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 17:00:50

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-28T18:10:41', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'dd756d6c-b8ae-4006-855b-c294c6b5aa5a' User entered 'None (1)'	System	28 Sep 2020 23:11:09
	System	28 Sep 2020 23:11:09

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-28T18:10:51', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'dd756d6c-b8ae-4006-855b-c294c6b5aa5a' User entered 'No (N)'	System	28 Sep 2020 23:11:09
	System	28 Sep 2020 23:11:09

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-28T18:10:55', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'dd756d6c-b8ae-4006-855b-c294c6b5aa5a' User entered 'No (N)'	System	28 Sep 2020 23:11:09
	System	28 Sep 2020 23:11:09

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-28T18:11:03', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'dd756d6c-b8ae-4006-855b-c294c6b5aa5a' User entered 'None (1)'	System	28 Sep 2020 23:11:09
	System	28 Sep 2020 23:11:09

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-28T18:11:06', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'dd756d6c-b8ae-4006-855b-c294c6b5aa5a' User entered '28 Sep 2020 18:11'	System	28 Sep 2020 23:11:09
	System	28 Sep 2020 23:11:09

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '28 Sep 2020 16:23'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '28 Sep 2020 18:53'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T07:56:51', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '5a944f8b-5213-4a53-bc3e-401b2d3cb6e1' User entered 'None (1)'	System	29 Sep 2020 12:57:28
	System	29 Sep 2020 12:57:28

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T07:56:56', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '5a944f8b-5213-4a53-bc3e-401b2d3cb6e1' User entered 'No (N)'	System	29 Sep 2020 12:57:28
	System	29 Sep 2020 12:57:28

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T07:57:08', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '5a944f8b-5213-4a53-bc3e-401b2d3cb6e1' User entered 'No (N)'	System	29 Sep 2020 12:57:28
	System	29 Sep 2020 12:57:28

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T07:57:20', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '5a944f8b-5213-4a53-bc3e-401b2d3cb6e1' User entered 'None (1)'	System	29 Sep 2020 12:57:28
	System	29 Sep 2020 12:57:28

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T07:57:23', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '5a944f8b-5213-4a53-bc3e-401b2d3cb6e1' User entered '29 Sep 2020 07:57'	System	29 Sep 2020 12:57:28
	System	29 Sep 2020 12:57:28

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '28 Sep 2020 19:48'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 2'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T12:00:57', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e1934695-e450-4c1f-8545-182fa4218ddc' User entered 'None (1)'	System	29 Sep 2020 17:01:28
	System	29 Sep 2020 17:01:28

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:16:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T12:01:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e1934695-e450-4c1f-8545-182fa4218ddc' User entered 'No (N)'	System	29 Sep 2020 17:01:28
	System	29 Sep 2020 17:01:28

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T12:01:03', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e1934695-e450-4c1f-8545-182fa4218ddc' User entered 'No (N)'	System	29 Sep 2020 17:01:28
	System	29 Sep 2020 17:01:28

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T12:01:08', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e1934695-e450-4c1f-8545-182fa4218ddc'	System	29 Sep 2020 17:01:28
User entered 'None (1)'	System	29 Sep 2020 17:01:28

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T12:01:12', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e1934695-e450-4c1f-8545-182fa4218ddc' User entered '29 Sep 2020 12:01'	System	29 Sep 2020 17:01:28
	System	29 Sep 2020 17:01:28

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 3'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-30T23:06:04', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '6675ba9e-5724-4bbd-a22a-fe7e4c06ad19' User entered 'None (1)'	System	01 Oct 2020 04:06:19
	System	01 Oct 2020 04:06:19

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:16:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-30T23:06:08', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '6675ba9e-5724-4bbd-a22a-fe7e4c06ad19' User entered 'No (N)'	System	01 Oct 2020 04:06:19
	System	01 Oct 2020 04:06:19

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-30T23:06:11', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '6675ba9e-5724-4bbd-a22a-fe7e4c06ad19' User entered 'No (N)'	System	01 Oct 2020 04:06:19
	System	01 Oct 2020 04:06:19

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-30T23:06:14', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '6675ba9e-5724-4bbd-a22a-fe7e4c06ad19' User entered 'None (1)'	System	01 Oct 2020 04:06:19
	System	01 Oct 2020 04:06:19

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-30T23:06:18', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '6675ba9e-5724-4bbd-a22a-fe7e4c06ad19' User entered '30 Sep 2020 23:06'	System	01 Oct 2020 04:06:19
	System	01 Oct 2020 04:06:19

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 21:16:11

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 4'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-01T12:01:19', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e777e05c-05fa-40fc-98df-e6f8eb0476cb' User entered 'None (1)'	System	01 Oct 2020 17:02:17
	System	01 Oct 2020 17:02:17

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:16:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-01T12:01:24', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e777e05c-05fa-40fc-98df-e6f8eb0476cb' User entered 'No (N)'	System	01 Oct 2020 17:02:17
	System	01 Oct 2020 17:02:17

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-01T12:01:27', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e777e05c-05fa-40fc-98df-e6f8eb0476cb' User entered 'No (N)'	System	01 Oct 2020 17:02:17
	System	01 Oct 2020 17:02:17

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-01T12:01:30', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e777e05c-05fa-40fc-98df-e6f8eb0476cb' User entered 'None (1)'	System	01 Oct 2020 17:02:17
	System	01 Oct 2020 17:02:17

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-01T12:01:34', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e777e05c-05fa-40fc-98df-e6f8eb0476cb' User entered '01 Oct 2020 12:01'	System	01 Oct 2020 17:02:17
	System	01 Oct 2020 17:02:17

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 5'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-02T12:55:37', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'ebd13084-6bcc-4ad9-a93a-a1c56bcc425e' User entered 'None (1)'	System	02 Oct 2020 17:55:53
	System	02 Oct 2020 17:55:53

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:16:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-02T12:55:41', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'ebd13084-6bcc-4ad9-a93a-a1c56bcc425e' User entered 'No (N)'	System	02 Oct 2020 17:55:53
	System	02 Oct 2020 17:55:53

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-02T12:55:45', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'ebd13084-6bcc-4ad9-a93a-a1c56bcc425e' User entered 'No (N)'	System	02 Oct 2020 17:55:53
	System	02 Oct 2020 17:55:53

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-02T12:55:48', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'ebd13084-6bcc-4ad9-a93a-a1c56bcc425e' User entered 'None (1)'	System	02 Oct 2020 17:55:53
	System	02 Oct 2020 17:55:53

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-02T12:55:51', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'ebd13084-6bcc-4ad9-a93a-a1c56bcc425e' User entered '02 Oct 2020 12:55'	System	02 Oct 2020 17:55:53
	System	02 Oct 2020 17:55:53

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 21:16:11

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 6'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-03T18:56:19', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '13165384-6e9a-484f-95c2-d261d8e38579' User entered 'None (1)'	System	03 Oct 2020 23:56:36
	System	03 Oct 2020 23:56:36

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:16:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-03T18:56:23', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '13165384-6e9a-484f-95c2-d261d8e38579' User entered 'No (N)'	System	03 Oct 2020 23:56:36
	System	03 Oct 2020 23:56:36

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-03T18:56:26', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '13165384-6e9a-484f-95c2-d261d8e38579' User entered 'No (N)'	System	03 Oct 2020 23:56:36
	System	03 Oct 2020 23:56:36

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-03T18:56:28', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '13165384-6e9a-484f-95c2-d261d8e38579' User entered 'None (1)'	System	03 Oct 2020 23:56:36
	System	03 Oct 2020 23:56:36

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-03T18:56:31', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '13165384-6e9a-484f-95c2-d261d8e38579' User entered '03 Oct 2020 18:56'	System	03 Oct 2020 23:56:36
	System	03 Oct 2020 23:56:36

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 11 Jun 2021 15:16:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 21:16:11

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 7'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-04T12:00:44', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '9a2b2a32-7247-433f-bfc6-8d9f81c64a9d'	System	04 Oct 2020 17:01:17
User entered 'None (1)'	System	04 Oct 2020 17:01:17

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:16:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-04T12:00:48', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '9a2b2a32-7247-433f-bfc6-8d9f81c64a9d' User entered 'No (N)'	System	04 Oct 2020 17:01:17
	System	04 Oct 2020 17:01:17

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:16:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-04T12:00:52', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '9a2b2a32-7247-433f-bfc6-8d9f81c64a9d' User entered 'No (N)'	System	04 Oct 2020 17:01:17
	System	04 Oct 2020 17:01:17

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:16:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-04T12:00:58', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '9a2b2a32-7247-433f-bfc6-8d9f81c64a9d' User entered 'None (1)'	System	04 Oct 2020 17:01:17
	System	04 Oct 2020 17:01:17

US3862099

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 11 Jun 2021 15:16:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-04T12:01:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '9a2b2a32-7247-433f-bfc6-8d9f81c64a9d' User entered '04 Oct 2020 12:01'	System	04 Oct 2020 17:01:17
	System	04 Oct 2020 17:01:17

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 21:16:11

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-28T18:11:12', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'd3ba4166-2dcd-45a2-92a5-89f9c26ac828'	System	28 Sep 2020 23:11:44
User entered 'No interference with activity (1)'	System	28 Sep 2020 23:11:44

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-28T18:11:19', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'd3ba4166-2dcd-45a2-92a5-89f9c26ac828' User entered 'None (0)'	System	28 Sep 2020 23:11:44
	System	28 Sep 2020 23:11:44

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-28T18:11:27', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'd3ba4166-2dcd-45a2-92a5-89f9c26ac828'	System	28 Sep 2020 23:11:44
User entered 'No interference with activity (1)'	System	28 Sep 2020 23:11:44

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-28T18:11:31', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'd3ba4166-2dcd-45a2-92a5-89f9c26ac828'	System	28 Sep 2020 23:11:44
User entered 'No interference with activity (1)'	System	28 Sep 2020 23:11:44

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-28T18:11:34', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'd3ba4166-2dcd-45a2-92a5-89f9c26ac828' User entered 'None (0)'	System	28 Sep 2020 23:11:44
	System	28 Sep 2020 23:11:44

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-28T18:11:36', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'd3ba4166-2dcd-45a2-92a5-89f9c26ac828' User entered 'None (0)'	System	28 Sep 2020 23:11:44
	System	28 Sep 2020 23:11:44

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

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)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-28T18:11:40', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'd3ba4166-2dcd-45a2-92a5-89f9c26ac828' User entered 'No (N)'	System	28 Sep 2020 23:11:44
	System	28 Sep 2020 23:11:44

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 11 Jun 2021 15:16:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-28T18:11:43', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'd3ba4166-2dcd-45a2-92a5-89f9c26ac828' User entered '28 Sep 2020 18:11'	System	28 Sep 2020 23:11:44
	System	28 Sep 2020 23:11:44

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '28 Sep 2020 16:23'	System	28 Sep 2020 21:16:11

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '28 Sep 2020 18:53'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 1, after vaccination (at home)'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T07:57:29', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'ba94138c-77e6-4591-b3a8-bb6e3f564dc6' User entered 'None (0)'	System	29 Sep 2020 12:57:51
	System	29 Sep 2020 12:57:51

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T07:57:32', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'ba94138c-77e6-4591-b3a8-bb6e3f564dc6' User entered 'None (0)'	System	29 Sep 2020 12:57:51
	System	29 Sep 2020 12:57:51

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T07:57:35', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'ba94138c-77e6-4591-b3a8-bb6e3f564dc6' User entered 'None (0)'	System	29 Sep 2020 12:57:51
	System	29 Sep 2020 12:57:51

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T07:57:38', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'ba94138c-77e6-4591-b3a8-bb6e3f564dc6' User entered 'None (0)'	System	29 Sep 2020 12:57:51
	System	29 Sep 2020 12:57:51

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T07:57:41', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'ba94138c-77e6-4591-b3a8-bb6e3f564dc6' User entered 'None (0)'	System	29 Sep 2020 12:57:51
	System	29 Sep 2020 12:57:51

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T07:57:43', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'ba94138c-77e6-4591-b3a8-bb6e3f564dc6' User entered 'None (0)'	System	29 Sep 2020 12:57:51
	System	29 Sep 2020 12:57:51

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

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)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T07:57:46', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'ba94138c-77e6-4591-b3a8-bb6e3f564dc6' User entered 'No (N)'	System	29 Sep 2020 12:57:51
	System	29 Sep 2020 12:57:51

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T07:57:49', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'ba94138c-77e6-4591-b3a8-bb6e3f564dc6' User entered '29 Sep 2020 07:57'	System	29 Sep 2020 12:57:51
	System	29 Sep 2020 12:57:51

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '28 Sep 2020 19:48'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '29 Sep 2020 11:59'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 2'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T12:01:19', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'da29d232-6ac2-4a8b-ad51-cf1dd4f6a117' User entered 'None (0)'	System	29 Sep 2020 17:02:00
	System	29 Sep 2020 17:02:00

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T12:01:22', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'da29d232-6ac2-4a8b-ad51-cf1dd4f6a117' User entered 'None (0)'	System	29 Sep 2020 17:02:00
	System	29 Sep 2020 17:02:00

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T12:01:24', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'da29d232-6ac2-4a8b-ad51-cf1dd4f6a117' User entered 'None (0)'	System	29 Sep 2020 17:02:00
	System	29 Sep 2020 17:02:00

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T12:01:28', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'da29d232-6ac2-4a8b-ad51-cf1dd4f6a117' User entered 'None (0)'	System	29 Sep 2020 17:02:00
	System	29 Sep 2020 17:02:00

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T12:01:30', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'da29d232-6ac2-4a8b-ad51-cf1dd4f6a117' User entered 'None (0)'	System	29 Sep 2020 17:02:00
	System	29 Sep 2020 17:02:00

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T12:01:32', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'da29d232-6ac2-4a8b-ad51-cf1dd4f6a117' User entered 'None (0)'	System	29 Sep 2020 17:02:00
	System	29 Sep 2020 17:02:00

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

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)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T12:01:35', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'da29d232-6ac2-4a8b-ad51-cf1dd4f6a117' User entered 'No (N)'	System	29 Sep 2020 17:02:00
	System	29 Sep 2020 17:02:00

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-29T12:01:43', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'da29d232-6ac2-4a8b-ad51-cf1dd4f6a117' User entered '29 Sep 2020 12:01'	System	29 Sep 2020 17:02:00
	System	29 Sep 2020 17:02:00

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '29 Sep 2020 12:00'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '30 Sep 2020 11:59'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 3'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-30T23:06:27', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'b7b06d4c-8761-4a86-803b-97ef87396c41'	System	01 Oct 2020 04:06:50
User entered 'No interference with activity (1)'	System	01 Oct 2020 04:06:50

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-30T23:06:31', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'b7b06d4c-8761-4a86-803b-97ef87396c41' User entered 'None (0)'	System	01 Oct 2020 04:06:50
	System	01 Oct 2020 04:06:50

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-30T23:06:34', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'b7b06d4c-8761-4a86-803b-97ef87396c41' User entered 'None (0)'	System	01 Oct 2020 04:06:50
	System	01 Oct 2020 04:06:50

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-30T23:06:37', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'b7b06d4c-8761-4a86-803b-97ef87396c41' User entered 'None (0)'	System	01 Oct 2020 04:06:50
	System	01 Oct 2020 04:06:50

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-30T23:06:40', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'b7b06d4c-8761-4a86-803b-97ef87396c41' User entered 'None (0)'	System	01 Oct 2020 04:06:50
	System	01 Oct 2020 04:06:50

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-30T23:06:43', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'b7b06d4c-8761-4a86-803b-97ef87396c41' User entered 'None (0)'	System	01 Oct 2020 04:06:50
	System	01 Oct 2020 04:06:50

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

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)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-30T23:06:46', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'b7b06d4c-8761-4a86-803b-97ef87396c41' User entered 'No (N)'	System	01 Oct 2020 04:06:50
	System	01 Oct 2020 04:06:50

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-09-30T23:06:49', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'b7b06d4c-8761-4a86-803b-97ef87396c41' User entered '30 Sep 2020 23:06'	System	01 Oct 2020 04:06:50
	System	01 Oct 2020 04:06:50

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '30 Sep 2020 12:00'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '01 Oct 2020 11:59'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 4'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-01T12:01:44', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'bfc0d620-fa14-435f-9e58-87e3b1a03293' User entered 'None (0)'	System	01 Oct 2020 17:03:09
	System	01 Oct 2020 17:03:09

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-01T12:01:47', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'bfc0d620-fa14-435f-9e58-87e3b1a03293' User entered 'None (0)'	System	01 Oct 2020 17:03:09
	System	01 Oct 2020 17:03:09

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-01T12:01:49', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'bfc0d620-fa14-435f-9e58-87e3b1a03293' User entered 'None (0)'	System	01 Oct 2020 17:03:09
	System	01 Oct 2020 17:03:09

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-01T12:01:53', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'bfc0d620-fa14-435f-9e58-87e3b1a03293' User entered 'None (0)'	System	01 Oct 2020 17:03:09
	System	01 Oct 2020 17:03:09

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-01T12:01:55', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'bfc0d620-fa14-435f-9e58-87e3b1a03293' User entered 'None (0)'	System	01 Oct 2020 17:03:09
	System	01 Oct 2020 17:03:09

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:16:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-01T12:01:58', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'bfc0d620-fa14-435f-9e58-87e3b1a03293' User entered 'None (0)'	System	01 Oct 2020 17:03:09
	System	01 Oct 2020 17:03:09

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 11 Jun 2021 15:16:15

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)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-01T12:02:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'bfc0d620-fa14-435f-9e58-87e3b1a03293' User entered 'No (N)'	System	01 Oct 2020 17:03:09
	System	01 Oct 2020 17:03:09

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-01T12:02:02', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'bfc0d620-fa14-435f-9e58-87e3b1a03293' User entered '01 Oct 2020 12:02'	System	01 Oct 2020 17:03:09
	System	01 Oct 2020 17:03:09

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '01 Oct 2020 12:00'	System	28 Sep 2020 21:16:11

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '02 Oct 2020 11:59'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 5'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-02T12:56:02', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '9513e76a-3a7c-40c9-8dac-150366791723'	System	02 Oct 2020 17:56:26
User entered 'No interference with activity (1)'	System	02 Oct 2020 17:56:26

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-02T12:56:05', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '9513e76a-3a7c-40c9-8dac-150366791723' User entered 'None (0)'	System	02 Oct 2020 17:56:26
	System	02 Oct 2020 17:56:26

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-02T12:56:09', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '9513e76a-3a7c-40c9-8dac-150366791723' User entered 'None (0)'	System	02 Oct 2020 17:56:26
	System	02 Oct 2020 17:56:26

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-02T12:56:13', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '9513e76a-3a7c-40c9-8dac-150366791723' User entered 'None (0)'	System	02 Oct 2020 17:56:26
	System	02 Oct 2020 17:56:26

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-02T12:56:15', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '9513e76a-3a7c-40c9-8dac-150366791723' User entered 'None (0)'	System	02 Oct 2020 17:56:26
	System	02 Oct 2020 17:56:26

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-02T12:56:17', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '9513e76a-3a7c-40c9-8dac-150366791723' User entered 'None (0)'	System	02 Oct 2020 17:56:26
	System	02 Oct 2020 17:56:26

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

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)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-02T12:56:20', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '9513e76a-3a7c-40c9-8dac-150366791723' User entered 'No (N)'	System	02 Oct 2020 17:56:26
	System	02 Oct 2020 17:56:26

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 11 Jun 2021 15:16:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-02T12:56:23', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '9513e76a-3a7c-40c9-8dac-150366791723' User entered '02 Oct 2020 12:56'	System	02 Oct 2020 17:56:26
	System	02 Oct 2020 17:56:26

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '02 Oct 2020 12:00'	System	28 Sep 2020 21:16:11

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '03 Oct 2020 11:59'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 6'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-03T18:56:35', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e4105a05-5039-455c-a8eb-537bf70e7f33' User entered 'None (0)'	System	03 Oct 2020 23:56:57
	System	03 Oct 2020 23:56:57

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-03T18:56:37', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e4105a05-5039-455c-a8eb-537bf70e7f33' User entered 'None (0)'	System	03 Oct 2020 23:56:57
	System	03 Oct 2020 23:56:57

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-03T18:56:39', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e4105a05-5039-455c-a8eb-537bf70e7f33' User entered 'None (0)'	System	03 Oct 2020 23:56:57
	System	03 Oct 2020 23:56:57

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-03T18:56:41', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e4105a05-5039-455c-a8eb-537bf70e7f33' User entered 'None (0)'	System	03 Oct 2020 23:56:57
	System	03 Oct 2020 23:56:57

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-03T18:56:43', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e4105a05-5039-455c-a8eb-537bf70e7f33' User entered 'None (0)'	System	03 Oct 2020 23:56:57
	System	03 Oct 2020 23:56:57

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-03T18:56:45', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e4105a05-5039-455c-a8eb-537bf70e7f33' User entered 'None (0)'	System	03 Oct 2020 23:56:57
	System	03 Oct 2020 23:56:57

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 11 Jun 2021 15:16:15

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)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-03T18:56:54', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e4105a05-5039-455c-a8eb-537bf70e7f33'	System	03 Oct 2020 23:56:57
User entered 'No (N)'	System	03 Oct 2020 23:56:57

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-03T18:56:56', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e4105a05-5039-455c-a8eb-537bf70e7f33' User entered '03 Oct 2020 18:56'	System	03 Oct 2020 23:56:57
	System	03 Oct 2020 23:56:57

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '03 Oct 2020 12:00'	System	28 Sep 2020 21:16:11

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '04 Oct 2020 11:59'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	28 Sep 2020 21:16:11
User entered 'Day 7'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-04T12:01:04', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8cb39593-83d0-4b54-961c-598cfeaf6a1' User entered 'None (0)'	System	04 Oct 2020 17:01:40
	System	04 Oct 2020 17:01:40

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-04T12:01:07', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8cb39593-83d0-4b54-961c-598cfeaef6a1' User entered 'None (0)'	System	04 Oct 2020 17:01:40
	System	04 Oct 2020 17:01:40

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-04T12:01:09', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8cb39593-83d0-4b54-961c-598cfeaef6a1' User entered 'None (0)'	System	04 Oct 2020 17:01:40
	System	04 Oct 2020 17:01:40

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-04T12:01:11', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8cb39593-83d0-4b54-961c-598cfeaf6a1' User entered 'None (0)'	System	04 Oct 2020 17:01:40
	System	04 Oct 2020 17:01:40

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-04T12:01:13', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8cb39593-83d0-4b54-961c-598cfeaf6a1' User entered 'None (0)'	System	04 Oct 2020 17:01:40
	System	04 Oct 2020 17:01:40

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:16:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-04T12:01:15', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8cb39593-83d0-4b54-961c-598cfeaf6a1' User entered 'None (0)'	System	04 Oct 2020 17:01:40
	System	04 Oct 2020 17:01:40

US3862099

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 11 Jun 2021 15:16:15

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)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-04T12:01:18', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8cb39593-83d0-4b54-961c-598cfeaf6a1' User entered 'No (N)'	System	04 Oct 2020 17:01:40
	System	04 Oct 2020 17:01:40

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-04T12:01:20', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8cb39593-83d0-4b54-961c-598cfeaf6a1' User entered '04 Oct 2020 12:01'	System	04 Oct 2020 17:01:40
	System	04 Oct 2020 17:01:40

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '04 Oct 2020 12:00'	System	28 Sep 2020 21:16:11

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '05 Oct 2020 11:59'	System	28 Sep 2020 21:16:11

US3862099

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	04 Oct 2020 17:00:50
User entered 'Day 8'	System	04 Oct 2020 17:00:50

US3862099

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Jun 2021 15:16:15

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)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-06T07:08:49', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '409f22a3-9d30-4d28-adab-4b5c3f5d1ff9' User entered 'No (N)'	System	06 Oct 2020 12:08:56
	System	06 Oct 2020 12:08:56

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-10-06T07:08:53', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '409f22a3-9d30-4d28-adab-4b5c3f5d1ff9' User entered '06 Oct 2020 07:08'	System	06 Oct 2020 12:08:56
	System	06 Oct 2020 12:08:56

**US3862099**

**Folder: Diary Dose 2 (1)**

**Form: Medical Attention\_Day(8)**

**Generated On: 11 Jun 2021 15:16:15**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '05 Oct 2020 12:00'	System	04 Oct 2020 17:00:50

US3862099

Folder: Diary Dose 2 (1)

Form: Medical Attention\_Day(8)

Generated On: 11 Jun 2021 15:16:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
User entered '06 Oct 2020 11:59'	System	04 Oct 2020 17:00:50

**US3862099**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 16:12:38

**US3862099**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '6 Oct 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 16:12:38

**US3862099**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 16:12:38

US3862099

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:16:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 16:12:38

US3862099

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:16:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	06 Oct 2020 16:12:43

**US3862099**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:16:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User entered 'I'	System	06 Oct 2020 16:12:43

**US3862099**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	12 Oct 2020 21:33:51

**US3862099**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '12 Oct 2020'	(b) (4) Sandra Francisco (b) (4)	12 Oct 2020 21:33:51

**US3862099**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sandra Francisco (b) (4)	12 Oct 2020 21:33:51

US3862099

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:16:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Sandra Francisco (b) (4)	12 Oct 2020 21:33:51

US3862099

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:16:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4)	19 Oct 2020 22:03:09

**US3862099**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:16:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User entered 'I'	System	19 Oct 2020 22:03:09

**US3862099**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4)	19 Oct 2020 22:03:20

**US3862099**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '19 Oct 2020'	(b) (4) Sandra Francisco (b) (4) (b) (4)	19 Oct 2020 22:03:20

**US3862099**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sandra Francisco (b) (4)	19 Oct 2020 22:03:20

US3862099

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:16:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Sandra Francisco (b) (4)	19 Oct 2020 22:03:20

US3862099

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:16:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	26 Oct 2020 18:39:28

**US3862099**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:16:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User entered 'I'	System	26 Oct 2020 18:39:28

US3862099

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:16:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 20:09:46

US3862099

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:16:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '28 Oct 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 20:09:46

US3862099

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:16:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 20:09:46

**US3862099**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 11 Jun 2021 15:16:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'VISIT3'	System	28 Oct 2020 20:09:46

**US3862099**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:16:15**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 21:08:34

US3862099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '28 Oct 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 21:08:34

**US3862099**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:16:15**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '14:25'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 21:08:34

**US3862099**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:16:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered '28 Oct 2020 14:25'	System	28 Oct 2020 21:08:34

US3862099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '98.8' F	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 21:08:34

US3862099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Other (Other)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 21:08:34

**US3862099**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:16:15**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'temporal'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 21:08:34

**US3862099**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:16:15**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '83'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 21:08:34

**US3862099**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:16:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'bpm'	System	28 Oct 2020 21:08:34

US3862099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '16'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 21:08:34

US3862099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'breaths/min'	System	28 Oct 2020 21:08:34

US3862099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '120'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 21:08:34

US3862099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'mmHg'	System	28 Oct 2020 21:08:34

**US3862099**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:16:15**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '64'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 21:08:34

**US3862099**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:16:15**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'mmHg'	System	28 Oct 2020 21:08:34

US3862099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16

US3862099

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16

US3862099

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:16:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 21:08:41

US3862099

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:16:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 21:08:41

US3862099

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:16:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User closed query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 28OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 10:14:27
Query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 28OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' answered with 'PPD status shipped from site. In Transit.' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	06 Nov 2020 18:49:29
User opened query 'Per GCL Lab Reconciliation: Was the sample collected? Is Yes for Visit 3 Day 57 with a Collection Date of 28OCT2020, however, there is no record of this sample, per GCL. Please clarify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 18:30:13
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 21:08:49

US3862099

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:16:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '28 Oct 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 21:08:49

**US3862099**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Jun 2021 15:16:15**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered '14:52'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 21:08:49

US3862099

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:16:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered '28 Oct 2020 14:52'	System	28 Oct 2020 21:08:49

US3862099

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:16:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:39:47
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 21:08:52

**US3862099**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:16:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:16
User entered 'I'	System	28 Oct 2020 21:08:52

US3862099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 64'	System	31 Aug 2020 21:27:38

US3862099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

[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)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-11-02T11:34:31', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'c64dfeda-d0b4-4a6e-b6fb-334265791733' User entered 'No (N)'	System	02 Nov 2020 17:34:42
	System	02 Nov 2020 17:34:42

US3862099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

Have you been exposed to someone with 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)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-11-02T11:34:34', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'c64dfeda-d0b4-4a6e-b6fb-334265791733'	System	02 Nov 2020 17:34:42
User entered 'No (N)'	System	02 Nov 2020 17:34:42

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-11-02T11:34:39', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'c64dfeda-d0b4-4a6e-b6fb-334265791733' User entered '02 Nov 2020 11:34:39'	System	02 Nov 2020 17:34:42
	System	02 Nov 2020 17:34:42

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered '31 Oct 2020 00:01'	System	31 Aug 2020 21:27:38

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered '04 Nov 2020 23:59'	System	31 Aug 2020 21:27:38

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 71'	System	31 Aug 2020 21:27:38

US3862099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

[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)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-11-09T12:00:31', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '832da838-fa1a-47e3-ab79-fa7db4c8f57b'	System	09 Nov 2020 18:00:44
User entered 'No (N)'	System	09 Nov 2020 18:00:44

US3862099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

Have you been exposed to someone with 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)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-11-09T12:00:33', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '832da838-fa1a-47e3-ab79-fa7db4c8f57b'	System	09 Nov 2020 18:00:44
User entered 'No (N)'	System	09 Nov 2020 18:00:44

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-11-09T12:00:37', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '832da838-fa1a-47e3-ab79-fa7db4c8f57b' User entered '09 Nov 2020 12:00:37'	System	09 Nov 2020 18:00:44
	System	09 Nov 2020 18:00:44

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered '07 Nov 2020 00:01'	System	31 Aug 2020 21:27:38

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:39:08
Data entry locked.	System	31 Aug 2020 21:27:38
User entered '11 Nov 2020 23:59'	System	31 Aug 2020 21:27:38

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53
Data entry locked.	System	31 Aug 2020 21:27:38
User entered 'Day 78'	System	31 Aug 2020 21:27:38

US3862099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

[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 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

US3862099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

Have you been exposed to someone with 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 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Please 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 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

US3862099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

[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 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Please 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 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

US3862099

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 11 Jun 2021 15:16:15

[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 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Please 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 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53
Data entry locked.	System	31 Aug 2020 21:27:38
User entered '14 Nov 2020 00:01'	System	31 Aug 2020 21:27:38

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 21:18:53
Data entry locked.	System	31 Aug 2020 21:27:38
User entered '18 Nov 2020 23:59'	System	31 Aug 2020 21:27:38

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 82'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-11-20T20:03:57', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '306e74a2-4593-4498-8b3f-40b02bd9f4f9' User entered 'No (N)'	System	21 Nov 2020 02:04:13
	System	21 Nov 2020 02:04:13

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Have you been exposed to someone with 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 (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-11-20T20:04:01', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '306e74a2-4593-4498-8b3f-40b02bd9f4f9' User entered 'No (N)'	System	21 Nov 2020 02:04:13
	System	21 Nov 2020 02:04:13

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-11-20T20:04:08', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '306e74a2-4593-4498-8b3f-40b02bd9f4f9' User entered '20 Nov 2020 20:04:08'	System	21 Nov 2020 02:04:13
	System	21 Nov 2020 02:04:13

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '18 Nov 2020 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '22 Nov 2020 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-11-25T00:01:20', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '89515a72-9307-40ab-b330-efed2a646ae3' User entered 'No (N)'	System	25 Nov 2020 06:01:40
	System	25 Nov 2020 06:01:40

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Have you been exposed to someone with 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 (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-11-25T00:01:23', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '89515a72-9307-40ab-b330-efed2a646ae3' User entered 'No (N)'	System	25 Nov 2020 06:01:40
	System	25 Nov 2020 06:01:40

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-11-25T00:01:28', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '89515a72-9307-40ab-b330-efed2a646ae3' User entered '25 Nov 2020 00:01:28'	System	25 Nov 2020 06:01:40
	System	25 Nov 2020 06:01:40

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '25 Nov 2020 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '29 Nov 2020 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '02 Dec 2020 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '06 Dec 2020 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-12-09T00:01:25', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e3e0b85b-9772-47e8-849c-b38951574ff2' User entered 'No (N)'	System	09 Dec 2020 06:01:45
	System	09 Dec 2020 06:01:45

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Have you been exposed to someone with 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 (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-12-09T00:01:29', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e3e0b85b-9772-47e8-849c-b38951574ff2'	System	09 Dec 2020 06:01:45
User entered 'No (N)'	System	09 Dec 2020 06:01:45

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-12-09T00:01:34', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e3e0b85b-9772-47e8-849c-b38951574ff2' User entered '09 Dec 2020 00:01:34'	System	09 Dec 2020 06:01:45
	System	09 Dec 2020 06:01:45

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '09 Dec 2020 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '13 Dec 2020 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-12-16T00:59:12', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '58fe54a8-1319-45b8-9fbe-acd732b55bff' User entered 'No (N)'	System	16 Dec 2020 06:59:22
	System	16 Dec 2020 06:59:22

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Have you been exposed to someone with 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 (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-12-16T00:59:15', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '58fe54a8-1319-45b8-9fbe-acd732b55bff' User entered 'No (N)'	System	16 Dec 2020 06:59:22
	System	16 Dec 2020 06:59:22

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (21B48A08-C8E1-4AEA-B06E-DD9300E9DB97)', Time: '2020-12-16T00:59:18', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '58fe54a8-1319-45b8-9fbe-acd732b55bff' User entered '16 Dec 2020 00:59:18'	System	16 Dec 2020 06:59:22
	System	16 Dec 2020 06:59:22

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '16 Dec 2020 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '20 Dec 2020 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '23 Dec 2020 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '27 Dec 2020 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '30 Dec 2020 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '03 Jan 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '06 Jan 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '10 Jan 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-01-13T14:53:17', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'f686557b-f3f4-4089-9429-9f305d8e5a51' User entered 'No (N)'	System	13 Jan 2021 20:53:28
	System	13 Jan 2021 20:53:28

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Have you been exposed to someone with 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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-01-13T14:53:20', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'f686557b-f3f4-4089-9429-9f305d8e5a51'	System	13 Jan 2021 20:53:28
User entered 'No (N)'	System	13 Jan 2021 20:53:28

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-01-13T14:53:25', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'f686557b-f3f4-4089-9429-9f305d8e5a51'	System	13 Jan 2021 20:53:28
User entered '13 Jan 2021 14:53:25'	System	13 Jan 2021 20:53:28

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '13 Jan 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '17 Jan 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-01-20T00:01:38', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'f4398114-c23a-4ad5-950a-1860d14eaad3' User entered 'No (N)'	System	20 Jan 2021 06:01:54
	System	20 Jan 2021 06:01:54

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Have you been exposed to someone with 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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-01-20T00:01:41', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'f4398114-c23a-4ad5-950a-1860d14eaad3'	System	20 Jan 2021 06:01:54
User entered 'No (N)'	System	20 Jan 2021 06:01:54

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-01-20T00:01:47', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'f4398114-c23a-4ad5-950a-1860d14eaad3' User entered '20 Jan 2021 00:01:47'	System	20 Jan 2021 06:01:54
	System	20 Jan 2021 06:01:54

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '20 Jan 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '24 Jan 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-01-27T00:01:24', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '5986c27b-1829-4ad2-b259-6bcd6d288cb2'	System	27 Jan 2021 06:01:42
User entered 'No (N)'	System	27 Jan 2021 06:01:42

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Have you been exposed to someone with 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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-01-27T00:01:27', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '5986c27b-1829-4ad2-b259-6bcd6d288cb2'	System	27 Jan 2021 06:01:42
User entered 'No (N)'	System	27 Jan 2021 06:01:42

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-01-27T00:01:30', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '5986c27b-1829-4ad2-b259-6bcd6d288cb2'	System	27 Jan 2021 06:01:42
User entered '27 Jan 2021 00:01:30'	System	27 Jan 2021 06:01:42

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '27 Jan 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '31 Jan 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-02-03T00:32:41', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '9567106a-afa5-4889-b091-77d778d1a350' User entered 'No (N)'	System	03 Feb 2021 06:32:50
	System	03 Feb 2021 06:32:50

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Have you been exposed to someone with 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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-02-03T00:32:43', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '9567106a-afa5-4889-b091-77d778d1a350'	System	03 Feb 2021 06:32:50
User entered 'No (N)'	System	03 Feb 2021 06:32:50

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-02-03T00:32:47', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '9567106a-afa5-4889-b091-77d778d1a350' User entered '03 Feb 2021 00:32:47'	System	03 Feb 2021 06:32:50
	System	03 Feb 2021 06:32:50

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '03 Feb 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '07 Feb 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-02-10T00:01:37', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '32f43091-061e-4f5d-943c-71deb41ec850'	System	10 Feb 2021 06:11:15
User entered 'No (N)'	System	10 Feb 2021 06:11:15

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Have you been exposed to someone with 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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-02-10T00:01:40', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '32f43091-061e-4f5d-943c-71deb41ec850'	System	10 Feb 2021 06:11:15
User entered 'No (N)'	System	10 Feb 2021 06:11:15

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-02-10T00:01:44', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '32f43091-061e-4f5d-943c-71deb41ec850' User entered '10 Feb 2021 00:01:44'	System	10 Feb 2021 06:11:15
	System	10 Feb 2021 06:11:15

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '10 Feb 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '14 Feb 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-02-17T00:08:12', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '0abb9b15-0364-4b04-9d71-57dfeea312bf' User entered 'No (N)'	System	17 Feb 2021 06:08:24
	System	17 Feb 2021 06:08:24

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Have you been exposed to someone with 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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-02-17T00:08:17', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '0abb9b15-0364-4b04-9d71-57dfeea312bf' User entered 'No (N)'	System	17 Feb 2021 06:08:24
	System	17 Feb 2021 06:08:24

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-02-17T00:08:21', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '0abb9b15-0364-4b04-9d71-57dfeea312bf' User entered '17 Feb 2021 00:08:21'	System	17 Feb 2021 06:08:24
	System	17 Feb 2021 06:08:24

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '17 Feb 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '21 Feb 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-02-24T00:01:21', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '42795150-fbf9-46ef-a0f7-4a78b05320e6' User entered 'No (N)'	System	24 Feb 2021 06:01:31
	System	24 Feb 2021 06:01:31

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Have you been exposed to someone with 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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-02-24T00:01:23', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '42795150-fbf9-46ef-a0f7-4a78b05320e6' User entered 'No (N)'	System	24 Feb 2021 06:01:31
	System	24 Feb 2021 06:01:31

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-02-24T00:01:26', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '42795150-fbf9-46ef-a0f7-4a78b05320e6' User entered '24 Feb 2021 00:01:26'	System	24 Feb 2021 06:01:31
	System	24 Feb 2021 06:01:31

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '24 Feb 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '28 Feb 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-03-03T00:02:44-06:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'fd4fd8e3-096b-4821-9264-811462e2f46e'	System	03 Mar 2021 06:02:54
User entered 'No (N)'	System	03 Mar 2021 06:02:54

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Have you been exposed to someone with 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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-03-03T00:02:47-06:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'fd4fd8e3-096b-4821-9264-811462e2f46e'	System	03 Mar 2021 06:02:54
User entered 'No (N)'	System	03 Mar 2021 06:02:54

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-03-03T00:02:51-06:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'fd4fd8e3-096b-4821-9264-811462e2f46e' User entered '03 Mar 2021 00:02:51'	System	03 Mar 2021 06:02:54
	System	03 Mar 2021 06:02:54

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '03 Mar 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '07 Mar 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-03-10T00:03:04-06:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'b70978e6-e26e-41c1-9d3f-7b316540c35b'	System	10 Mar 2021 06:03:18
User entered 'No (N)'	System	10 Mar 2021 06:03:18

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Have you been exposed to someone with 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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-03-10T00:03:07-06:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'b70978e6-e26e-41c1-9d3f-7b316540c35b'	System	10 Mar 2021 06:03:18
User entered 'No (N)'	System	10 Mar 2021 06:03:18

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-03-10T00:03:11-06:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'b70978e6-e26e-41c1-9d3f-7b316540c35b' User entered '10 Mar 2021 00:03:11'	System	10 Mar 2021 06:03:18
	System	10 Mar 2021 06:03:18

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '10 Mar 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '14 Mar 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-03-17T00:29:10-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '2f1a8d1a-a2d2-4423-a834-ebfd1094f33b'	System	17 Mar 2021 05:30:35
User entered 'Yes (Y)'	System	17 Mar 2021 05:30:35

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Have you been exposed to someone with 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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-03-17T00:29:15-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '2f1a8d1a-a2d2-4423-a834-ebfd1094f33b'	System	17 Mar 2021 05:30:35
User entered 'No (N)'	System	17 Mar 2021 05:30:35

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-03-17T00:29:22-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '2f1a8d1a-a2d2-4423-a834-ebfd1094f33b'	System	17 Mar 2021 05:30:35
User entered 'No (N)'	System	17 Mar 2021 05:30:35

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-03-17T00:30:16-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '2f1a8d1a-a2d2-4423-a834-ebfd1094f33b'	System	17 Mar 2021 05:30:35
User entered 'Yes (Y)'	System	17 Mar 2021 05:30:35

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Please 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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-03-17T00:30:18-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '2f1a8d1a-a2d2-4423-a834-ebfd1094f33b'	System	17 Mar 2021 05:30:35
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Mar 2021 05:30:35

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-03-17T00:30:25-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '2f1a8d1a-a2d2-4423-a834-ebfd1094f33b' User entered '17 Mar 2021 00:30:25'	System	17 Mar 2021 05:30:35
	System	17 Mar 2021 05:30:35

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '17 Mar 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '21 Mar 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 21:18:53

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-03-24T00:02:28-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '1e5d90ac-39d6-496f-9e9b-6071243b468c' User entered 'No (N)'	System	24 Mar 2021 05:02:59
	System	24 Mar 2021 05:02:59

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Have you been exposed to someone with 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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-03-24T00:02:31-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '1e5d90ac-39d6-496f-9e9b-6071243b468c' User entered 'No (N)'	System	24 Mar 2021 05:02:59
	System	24 Mar 2021 05:02:59

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-03-24T00:02:35-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '1e5d90ac-39d6-496f-9e9b-6071243b468c' User entered '24 Mar 2021 00:02:35'	System	24 Mar 2021 05:02:59
	System	24 Mar 2021 05:02:59

**US3862099**

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

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '24 Mar 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '28 Mar 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-04-03T17:59:22-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8e1e62a9-92e0-448a-8c68-b4f3a8e826ce' User entered 'No (N)'	System	03 Apr 2021 22:59:30
	System	03 Apr 2021 22:59:30

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Have you been exposed to someone with 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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-04-03T17:59:25-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8e1e62a9-92e0-448a-8c68-b4f3a8e826ce' User entered 'No (N)'	System	03 Apr 2021 22:59:30
	System	03 Apr 2021 22:59:30

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-04-03T17:59:28-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '8e1e62a9-92e0-448a-8c68-b4f3a8e826ce' User entered '03 Apr 2021 17:59:28'	System	03 Apr 2021 22:59:30
	System	03 Apr 2021 22:59:30

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '31 Mar 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '04 Apr 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-04-07T00:46:12-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '673135da-f93e-4da8-87e1-a7453afdb01a' User entered 'No (N)'	System	07 Apr 2021 05:46:22
	System	07 Apr 2021 05:46:22

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Have you been exposed to someone with 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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-04-07T00:46:15-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '673135da-f93e-4da8-87e1-a7453afdb01a' User entered 'No (N)'	System	07 Apr 2021 05:46:22
	System	07 Apr 2021 05:46:22

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-04-07T00:46:20-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '673135da-f93e-4da8-87e1-a7453afdb01a' User entered '07 Apr 2021 00:46:20'	System	07 Apr 2021 05:46:22
	System	07 Apr 2021 05:46:22

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '07 Apr 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '11 Apr 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-04-14T00:02:26-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e562a07d-489f-44f4-9c39-34718f8d84bc' User entered 'Yes (Y)'	System	14 Apr 2021 05:02:59
	System	14 Apr 2021 05:02:59

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Have you been exposed to someone with 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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-04-14T00:02:30-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e562a07d-489f-44f4-9c39-34718f8d84bc'	System	14 Apr 2021 05:02:59
User entered 'No (N)'	System	14 Apr 2021 05:02:59

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-04-14T00:02:35-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e562a07d-489f-44f4-9c39-34718f8d84bc' User entered 'No (N)'	System	14 Apr 2021 05:02:59
	System	14 Apr 2021 05:02:59

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-04-14T00:02:42-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e562a07d-489f-44f4-9c39-34718f8d84bc'	System	14 Apr 2021 05:02:59
User entered 'Yes (Y)'	System	14 Apr 2021 05:02:59

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Please 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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-04-14T00:02:47-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e562a07d-489f-44f4-9c39-34718f8d84bc'	System	14 Apr 2021 05:02:59
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	14 Apr 2021 05:02:59

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-04-14T00:02:49-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: 'e562a07d-489f-44f4-9c39-34718f8d84bc'	System	14 Apr 2021 05:02:59
User entered '14 Apr 2021 00:02:49'	System	14 Apr 2021 05:02:59

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '14 Apr 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '18 Apr 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-04-21T00:02:26-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '899c735a-d8f4-4dfd-b8cc-c3577b6160f7'	System	21 Apr 2021 05:02:39
User entered 'No (N)'	System	21 Apr 2021 05:02:39

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Have you been exposed to someone with 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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-04-21T00:02:28-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '899c735a-d8f4-4dfd-b8cc-c3577b6160f7'	System	21 Apr 2021 05:02:39
User entered 'No (N)'	System	21 Apr 2021 05:02:39

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-04-21T00:02:31-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '899c735a-d8f4-4dfd-b8cc-c3577b6160f7'	System	21 Apr 2021 05:02:39
User entered '21 Apr 2021 00:02:31'	System	21 Apr 2021 05:02:39

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '21 Apr 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '25 Apr 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-04-28T00:02:14-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '3871ac6e-f634-4728-9d51-e25e4ec85df0'	System	29 Apr 2021 05:57:54
User entered 'No (N)'	System	29 Apr 2021 05:57:54

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

Have you been exposed to someone with 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 (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-04-28T00:02:17-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '3871ac6e-f634-4728-9d51-e25e4ec85df0'	System	29 Apr 2021 05:57:54
User entered 'No (N)'	System	29 Apr 2021 05:57:54

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-04-28T00:02:20-05:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '3871ac6e-f634-4728-9d51-e25e4ec85df0'	System	29 Apr 2021 05:57:54
User entered '28 Apr 2021 00:02:20'	System	29 Apr 2021 05:57:54

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '28 Apr 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '02 May 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '05 May 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '09 May 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '12 May 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '16 May 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '19 May 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '23 May 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '26 May 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '30 May 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '02 Jun 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '06 Jun 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '09 Jun 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '13 Jun 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '16 Jun 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '20 Jun 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '23 Jun 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '27 Jun 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '30 Jun 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '04 Jul 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '07 Jul 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '11 Jul 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '14 Jul 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '18 Jul 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '21 Jul 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '25 Jul 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '28 Jul 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '01 Aug 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '04 Aug 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '08 Aug 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '11 Aug 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '15 Aug 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '18 Aug 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '22 Aug 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '25 Aug 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '29 Aug 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '01 Sep 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '05 Sep 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '08 Sep 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '12 Sep 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '15 Sep 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '19 Sep 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '22 Sep 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '26 Sep 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '29 Sep 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '03 Oct 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '06 Oct 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '10 Oct 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '13 Oct 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '17 Oct 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '20 Oct 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '24 Oct 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '27 Oct 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '31 Oct 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '03 Nov 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '07 Nov 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '10 Nov 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '14 Nov 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '17 Nov 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '21 Nov 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '24 Nov 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '28 Nov 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '01 Dec 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '05 Dec 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '08 Dec 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '12 Dec 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '15 Dec 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '19 Dec 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '22 Dec 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '26 Dec 2021 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '29 Dec 2021 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '02 Jan 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '05 Jan 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '09 Jan 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '12 Jan 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '16 Jan 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '19 Jan 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '23 Jan 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '26 Jan 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '30 Jan 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '02 Feb 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '06 Feb 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '09 Feb 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '13 Feb 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '16 Feb 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '20 Feb 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '23 Feb 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '27 Feb 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '02 Mar 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '06 Mar 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '09 Mar 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '13 Mar 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '16 Mar 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '20 Mar 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '23 Mar 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '27 Mar 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '30 Mar 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '03 Apr 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '06 Apr 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '10 Apr 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '13 Apr 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '17 Apr 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '20 Apr 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '24 Apr 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '27 Apr 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '01 May 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '04 May 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '08 May 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '11 May 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '15 May 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '18 May 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '22 May 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '25 May 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '29 May 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '01 Jun 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '05 Jun 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '08 Jun 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '12 Jun 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '15 Jun 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '19 Jun 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '22 Jun 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '26 Jun 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '29 Jun 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '03 Jul 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '06 Jul 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '10 Jul 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '13 Jul 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '17 Jul 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '20 Jul 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '24 Jul 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '27 Jul 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '31 Jul 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '03 Aug 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '07 Aug 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '10 Aug 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '14 Aug 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '17 Aug 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '21 Aug 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '24 Aug 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '28 Aug 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '31 Aug 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '04 Sep 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '07 Sep 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '11 Sep 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '14 Sep 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '18 Sep 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '21 Sep 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '25 Sep 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '28 Sep 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '02 Oct 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '05 Oct 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '09 Oct 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '12 Oct 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '16 Oct 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '19 Oct 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '23 Oct 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '26 Oct 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '30 Oct 2022 23:59'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '02 Nov 2022 00:01'	System	19 Nov 2020 21:18:53

**US3862099**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 11 Jun 2021 15:16:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 21:18:53
Amendment Manager: User entered '06 Nov 2022 23:59'	System	19 Nov 2020 21:18:53

US3862099

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 11 Jun 2021 15:16:15**

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 21:19:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-03-03T00:03:08-06:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '294160dd-997d-469f-a939-baf07b152684'	System	03 Mar 2021 06:03:26
User entered 'No (N)'	System	03 Mar 2021 06:03:26

US3862099

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 11 Jun 2021 15:16:15

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:19:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (206EB21C-0F1A-455D-AE64-825AE5D6B492)', Time: '2021-03-03T00:03:24-06:00', User OID: 'PatientReportedOutcome (US3862099)', ODM File OID: '294160dd-997d-469f-a939-baf07b152684' User entered '03 Mar 2021 00:03:24'	System	03 Mar 2021 06:03:26
	System	03 Mar 2021 06:03:26

**US3862099**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:29:15
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Nov 2020 19:23:36

**US3862099**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:29:15
User entered '25 Nov 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Nov 2020 19:23:36

**US3862099**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:29:15
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Nov 2020 19:23:36

**US3862099**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:29:15
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Nov 2020 19:23:36

US3862099

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:16:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:29:15
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Nov 2020 19:23:40

**US3862099**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:16:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:53:08
User entered 'I'	System	25 Nov 2020 19:23:40

**US3862099**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	28 Dec 2020 21:35:00

**US3862099**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '28 Dec 2020'	(b) (4) Trent Davis (b) (4)	28 Dec 2020 21:35:00
	(b) (4)	

**US3862099**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Trent Davis (b) (4)	28 Dec 2020 21:35:00

US3862099

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:16:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4)	28 Dec 2020 21:35:00
	Trent Davis (b) (4)	
	(b) (4)	

US3862099

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:16:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:48
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	29 Dec 2020 15:38:30

**US3862099**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:16:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:48
User entered 'I'	System	29 Dec 2020 15:38:30

**US3862099**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Jan 2021 18:12:36

**US3862099**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '29 Jan 2021'	(b) (4), (b) (6)	29 Jan 2021 18:12:36

**US3862099**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	29 Jan 2021 18:12:36

**US3862099**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4), (b) (6)	29 Jan 2021 18:12:36

**US3862099**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:16:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 18:12:46

**US3862099**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:16:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User entered 'I'	System	29 Jan 2021 18:12:46

**US3862099**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	24 Mar 2021 22:04:38

US3862099

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:16:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User closed query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6)	01 Apr 2021 03:16:37
Query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'MADE OUT OF WINDOW. PD CREATED.' (Site from System).	Carrie Kibler (b) (4) (b) (4)	24 Mar 2021 22:04:54
User opened query 'Safety Call Day 179 'Date of Contact or Contact Attempt' is less than 147 days or greater than 153 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	24 Mar 2021 22:04:38
User entered '19 Feb 2021'	Carrie Kibler (b) (4) (b) (4)	24 Mar 2021 22:04:38

**US3862099**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carrie Kibler (b) (4)	24 Mar 2021 22:04:38

**US3862099**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	24 Mar 2021 22:04:38

US3862099

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:16:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	24 Mar 2021 22:04:58

**US3862099**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:16:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User entered 'I'	System	24 Mar 2021 22:04:58

**US3862099**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Jun 2021 15:16:15**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Mar 2021 21:32:56

**US3862099**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Jun 2021 15:16:15**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '25 Mar 2021'	(b) (4) Carrie Kibler (b) (4)	25 Mar 2021 21:32:56
	(b) (4)	

**US3862099**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Jun 2021 15:16:15**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Mar 2021 21:32:56

**US3862099**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 11 Jun 2021 15:16:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User entered 'VISIT4'	System	25 Mar 2021 21:32:56

**US3862099**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:16:15**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 22:56:29

US3862099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '25 Mar 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 22:56:29

US3862099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '14:57'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 22:56:29

**US3862099**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:16:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User entered '25 Mar 2021 14:57'	System	30 Mar 2021 22:56:29

US3862099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '97.7' F	(b) (4) Carrie Kibler (b) (4)	30 Mar 2021 22:56:29
	(b) (4)	

US3862099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Other (Other)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 22:56:29

**US3862099**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:16:15**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'temporal'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 22:56:29

**US3862099**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:16:15**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '62'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 22:56:29

**US3862099**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:16:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User entered 'bpm'	System	30 Mar 2021 22:56:29

**US3862099**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:16:15**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '15'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 22:56:29

US3862099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User entered 'breaths/min'	System	30 Mar 2021 22:56:29

US3862099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '111'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 22:56:29

US3862099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User entered 'mmHg'	System	30 Mar 2021 22:56:29

US3862099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '62'	(b) (4) Carrie Kibler (b) (4) (b) (4)	30 Mar 2021 22:56:29

US3862099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User entered 'mmHg'	System	30 Mar 2021 22:56:29

US3862099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49

US3862099

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49

**US3862099**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 11 Jun 2021 15:16:15**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	25 Mar 2021 21:33:04

US3862099

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:16:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '25 Mar 2021'	(b) (4) Carrie Kibler (b) (4)	25 Mar 2021 21:33:04
	(b) (4)	

**US3862099**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Jun 2021 15:16:15**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	25 Mar 2021 21:33:12
	(b) (4)	

US3862099

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:16:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '25 Mar 2021'	(b) (4) Carrie Kibler (b) (4)	25 Mar 2021 21:33:12
	(b) (4)	

**US3862099**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Jun 2021 15:16:15**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '15:10'	(b) (4) Carrie Kibler (b) (4)	25 Mar 2021 21:33:12
	(b) (4)	

**US3862099**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Jun 2021 15:16:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User entered '25 Mar 2021 15:10'	System	25 Mar 2021 21:33:12

US3862099

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:16:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	26 Mar 2021 19:51:07
	(b) (4)	

**US3862099**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:16:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:05:49
User entered 'I'	System	26 Mar 2021 19:51:07

**US3862099**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	26 Apr 2021 15:06:08
	(b) (4)	

US3862099

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:16:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
	(b) (4)	
User entered '23 Apr 2021'	Carrie Kibler (b) (4)	26 Apr 2021 15:06:08
	(b) (4)	

**US3862099**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Carrie Kibler (b) (4)	26 Apr 2021 15:06:08
	(b) (4)	

**US3862099**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	26 Apr 2021 15:06:08
	(b) (4)	

**US3862099**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:16:15**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	26 Apr 2021 15:05:59
	(b) (4)	

**US3862099**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:16:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 15:05:59

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:16:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	13 Jan 2021 21:05:20
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:16:15

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '13 Jan 2021'	Carrie Kibler (b) (4)	13 Jan 2021 21:05:20
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:16:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4)	13 Jan 2021 21:05:20
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:16:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'UNBLND_DECIDE'	System	13 Jan 2021 21:05:20

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 15:16:15

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '13 Jan 2021'	Carrie Kibler (b) (4)	13 Jan 2021 21:06:23
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 15:16:15

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 07:42:17

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 15:16:15

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	13 Jan 2021 21:06:23
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 15:16:15

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(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 07:42:17

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 15:16:15

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '13 Jan 2021'	Carrie Kibler (b) (4)	13 Jan 2021 21:06:23
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 15:16:15

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Placebo (Placebo)'	Carrie Kibler (b) (4)	13 Jan 2021 21:06:23
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 15:16:15

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 03:50:05
User entered 'Placebo (Placebo)'	Carrie Kibler (b) (4)	13 Jan 2021 21:06:23
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 15:16:15

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	System	20 Jan 2021 03:50:05
User entered 'Placebo (Placebo)'	Carrie Kibler (b) (4)	13 Jan 2021 21:06:23
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 15:16:15

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	13 Jan 2021 21:06:23
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 15:16:15

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'I'	System	13 Jan 2021 21:06:23

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 11 Jun 2021 15:16:15

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'I'	System	13 Jan 2021 21:06:23

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:16:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered missing code ND - Not Done.	Carrie Kibler (b) (4)	13 Jan 2021 22:20:43
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:16:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered missing code ND - Not Done.	Carrie Kibler (b) (4)	13 Jan 2021 22:20:43
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:16:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered empty.	System	13 Jan 2021 22:20:43
DataPoint set to visible.	System	13 Jan 2021 21:06:23

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:16:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered missing code ND - Not Done.	Carrie Kibler (b) (4)	13 Jan 2021 22:20:43
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:16:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered missing code ND - Not Done.	Carrie Kibler (b) (4)	13 Jan 2021 22:20:43
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:16:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered empty.	System	13 Jan 2021 22:20:43
DataPoint set to visible.	System	13 Jan 2021 21:06:23

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User accepted default value 'Pre-Dose (PREDOSE)'	Carrie Kibler (b) (4)	13 Jan 2021 22:20:43
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	13 Jan 2021 22:20:43
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '13 Jan 2021'	Carrie Kibler (b) (4)	13 Jan 2021 22:20:43
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '14:36'	Carrie Kibler (b) (4)	13 Jan 2021 22:20:43
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered '13 Jan 2021 14:36'	System	13 Jan 2021 22:20:43

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '98.3' F	Carrie Kibler (b) (4)	13 Jan 2021 22:20:43
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Other (Other)'	Carrie Kibler (b) (4)	13 Jan 2021 22:20:43
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'temporal'	Carrie Kibler (b) (4)	13 Jan 2021 22:20:43
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '81'	Carrie Kibler (b) (4)	13 Jan 2021 22:20:43
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'bpm'	System	13 Jan 2021 22:20:43

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '16'	Carrie Kibler (b) (4)	13 Jan 2021 22:20:43
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'breaths/min'	System	13 Jan 2021 22:20:43

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '106'	Carrie Kibler (b) (4)	13 Jan 2021 22:20:43
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'mmHg'	System	13 Jan 2021 22:20:43

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '71'	Carrie Kibler (b) (4)	13 Jan 2021 22:20:43
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'mmHg'	System	13 Jan 2021 22:20:43

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:16:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered missing code ND - Not Done.	Carrie Kibler (b) (4)	13 Jan 2021 22:20:43
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:16:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered missing code ND - Not Done.	Carrie Kibler (b) (4)	13 Jan 2021 22:20:43
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 11 Jun 2021 15:16:15

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered empty.	System	13 Jan 2021 22:20:43
DataPoint set to visible.	System	13 Jan 2021 21:06:23

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User accepted default value 'Post-Dose (POSTDOSE)'	Carrie Kibler (b) (4)	13 Jan 2021 22:21:25
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	13 Jan 2021 22:21:25
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '13 Jan 2021'	Carrie Kibler (b) (4)	13 Jan 2021 22:21:25
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '16:08'	Carrie Kibler (b) (4)	13 Jan 2021 22:21:25
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered '13 Jan 2021 16:08'	System	13 Jan 2021 22:21:25

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '98.8' F	Carrie Kibler (b) (4)	13 Jan 2021 22:21:25
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Other (Other)'	Carrie Kibler (b) (4)	13 Jan 2021 22:21:25
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'temporal'	Carrie Kibler (b) (4)	13 Jan 2021 22:21:25
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '78'	Carrie Kibler (b) (4)	13 Jan 2021 22:21:25
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'bpm'	System	13 Jan 2021 22:21:25

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '16'	Carrie Kibler (b) (4)	13 Jan 2021 22:21:25
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'breaths/min'	System	13 Jan 2021 22:21:25

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '127'	Carrie Kibler (b) (4)	13 Jan 2021 22:21:25
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'mmHg'	System	13 Jan 2021 22:21:25

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '79'	Carrie Kibler (b) (4)	13 Jan 2021 22:21:25
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'mmHg'	System	13 Jan 2021 22:21:25

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:16:15

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	13 Jan 2021 21:06:37
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:16:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '13 Jan 2021'	Carrie Kibler (b) (4)	13 Jan 2021 21:06:37
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	13 Jan 2021 22:19:20
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Jan 2021 22:19:20
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

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)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	13 Jan 2021 22:19:20
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'mRNA-1273'	System	13 Jan 2021 22:19:20
DataPoint set to visible.	System	13 Jan 2021 21:06:23

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '13 Jan 2021'	Carrie Kibler (b) (4)	13 Jan 2021 22:19:20
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '15:36'	Carrie Kibler (b) (4)	13 Jan 2021 22:19:20
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered '13 Jan 2021 15:36'	System	13 Jan 2021 22:19:20

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Carrie Kibler (b) (4)	13 Jan 2021 22:19:20
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'ONCE'	System	13 Jan 2021 22:19:20

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'INTRAMUSCULAR'	System	13 Jan 2021 22:19:20

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:16:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	13 Jan 2021 22:19:40
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:16:15

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '13 Jan 2021'	Carrie Kibler (b) (4)	13 Jan 2021 22:19:40
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:16:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '14:44'	Carrie Kibler (b) (4)	13 Jan 2021 22:19:40
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:16:15

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered '13 Jan 2021 14:44'	System	13 Jan 2021 22:19:40

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 15:16:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	13 Jan 2021 22:20:06
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 15:16:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '13 Jan 2021'	Carrie Kibler (b) (4)	13 Jan 2021 22:20:06
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 11 Jun 2021 15:16:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '14:42'	Carrie Kibler (b) (4)	13 Jan 2021 22:20:06
	(b) (4)	

**US3862099**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 11 Jun 2021 15:16:15**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered '13 Jan 2021 14:42'	System	13 Jan 2021 22:20:06

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:16:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	13 Jan 2021 21:06:47
	(b) (4)	

US3862099

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:16:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'I'	System	13 Jan 2021 21:06:47

US3862099

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:16:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	20 Jan 2021 14:47:14
	(b) (4)	

US3862099

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:16:15

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '20 Jan 2021'	Thea Marie Cordero	20 Jan 2021 14:47:14
	(b) (4)	

US3862099

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:16:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Thea Marie Cordero	20 Jan 2021 14:47:14
	(b) (4)	

US3862099

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:16:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Thea Marie Cordero	20 Jan 2021 14:47:14
	(b) (4)	

US3862099

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:16:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	20 Jan 2021 14:47:18
	(b) (4)	

**US3862099**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:16:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'I'	System	20 Jan 2021 14:47:18

**US3862099**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:16:15**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'I'	System	20 Jan 2021 14:47:18
DataPoint set to visible.	System	20 Jan 2021 14:47:18

US3862099

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:16:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	12 Feb 2021 18:30:53
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:16:15

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '12 Feb 2021'	Carrie Kibler (b) (4)	12 Feb 2021 18:30:53
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:16:15

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4)	12 Feb 2021 18:30:53
	(b) (4)	

**US3862099**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 11 Jun 2021 15:16:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'OLD29'	System	12 Feb 2021 18:30:53

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User accepted default value 'Pre-Dose (PREDOSE)'	Carrie Kibler (b) (4)	12 Feb 2021 18:59:30
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	12 Feb 2021 18:59:30
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '12 Feb 2021'	Carrie Kibler (b) (4)	12 Feb 2021 18:59:30
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '11:47'	Carrie Kibler (b) (4)	12 Feb 2021 18:59:30
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered '12 Feb 2021 11:47'	System	12 Feb 2021 18:59:30

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '97.7' F	Carrie Kibler (b) (4)	12 Feb 2021 18:59:30
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Other (Other)'	Carrie Kibler (b) (4)	12 Feb 2021 18:59:30
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Temporal'	Carrie Kibler (b) (4)	12 Feb 2021 18:59:30
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '70'	Carrie Kibler (b) (4)	12 Feb 2021 18:59:30
	(b) (4)	

**US3862099**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'bpm'	System	12 Feb 2021 18:59:30

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '16'	Carrie Kibler (b) (4)	12 Feb 2021 18:59:30
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'breaths/min'	System	12 Feb 2021 18:59:30

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '103'	Carrie Kibler (b) (4)	12 Feb 2021 18:59:30
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'mmHg'	System	12 Feb 2021 18:59:30

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 11 Jun 2021 15:16:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '65'	Carrie Kibler (b) (4)	12 Feb 2021 18:59:30
	(b) (4)	

**US3862099**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'mmHg'	System	12 Feb 2021 18:59:30

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User accepted default value 'Post-Dose (POSTDOSE)'	Carrie Kibler (b) (4)	13 Feb 2021 18:51:48
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	13 Feb 2021 18:51:48
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '12 Feb 2021'	Carrie Kibler (b) (4)	13 Feb 2021 18:51:48
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '13:11' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Feb 2021 18:56:58
	(b) (4)	
User entered '11:47'	Carrie Kibler (b) (4)	13 Feb 2021 18:51:48
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered '12 Feb 2021 13:11'	System	13 Feb 2021 18:56:58
User entered '12 Feb 2021 11:47'	System	13 Feb 2021 18:51:48

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '97.5' F reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Feb 2021 18:56:58
	(b) (4)	
User entered '97.7' F	Carrie Kibler (b) (4)	13 Feb 2021 18:51:48
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Other (Other)'	Carrie Kibler (b) (4)	13 Feb 2021 18:51:48
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'temporal'	Carrie Kibler (b) (4)	13 Feb 2021 18:51:48
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '64' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Feb 2021 18:56:58
	(b) (4)	
User entered '70'	Carrie Kibler (b) (4)	13 Feb 2021 18:51:48
	(b) (4)	

**US3862099**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'bpm'	System	13 Feb 2021 18:51:48

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '14' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Feb 2021 18:56:58
	(b) (4)	
User entered '16'	Carrie Kibler (b) (4)	13 Feb 2021 18:51:48
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'breaths/min'	System	13 Feb 2021 18:51:48

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '123' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Feb 2021 18:56:58
	(b) (4)	
User entered '103'	Carrie Kibler (b) (4)	13 Feb 2021 18:51:48
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'mmHg'	System	13 Feb 2021 18:51:48

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '68' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Feb 2021 18:56:58
	(b) (4)	
User entered '65'	Carrie Kibler (b) (4)	13 Feb 2021 18:51:48
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 11 Jun 2021 15:16:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'mmHg'	System	13 Feb 2021 18:51:48

US3862099

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:16:15

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	12 Feb 2021 18:31:02
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:16:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '12 Feb 2021'	Carrie Kibler (b) (4)	12 Feb 2021 18:31:02
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	12 Feb 2021 18:58:36
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	12 Feb 2021 18:58:36
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

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)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	12 Feb 2021 18:58:36
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'mRNA-1273'	System	12 Feb 2021 18:58:36
DataPoint set to visible.	System	20 Jan 2021 14:47:18

US3862099

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '12 Feb 2021'	Carrie Kibler (b) (4)	12 Feb 2021 18:58:36
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '12:41'	Carrie Kibler (b) (4)	12 Feb 2021 18:58:36
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered '12 Feb 2021 12:41'	System	12 Feb 2021 18:58:36

US3862099

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Carrie Kibler (b) (4)	12 Feb 2021 18:58:36
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'ONCE'	System	12 Feb 2021 18:58:36

US3862099

Folder: OL-D29 (1)

Form: Exposure

Generated On: 11 Jun 2021 15:16:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'INTRAMUSCULAR'	System	12 Feb 2021 18:58:36

US3862099

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:16:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	12 Feb 2021 18:30:45
	(b) (4)	

US3862099

Folder: OL-D29 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:16:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'I'	System	12 Feb 2021 18:30:45

US3862099

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:16:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	17 Mar 2021 14:03:27
	(b) (4)	

**US3862099**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '19 Feb 2021'	Thea Marie Cordero	17 Mar 2021 14:03:27
	(b) (4)	

US3862099

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 11 Jun 2021 15:16:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Thea Marie Cordero	17 Mar 2021 14:03:27
	(b) (4)	

**US3862099**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 11 Jun 2021 15:16:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Thea Marie Cordero	17 Mar 2021 14:03:27
	(b) (4)	

US3862099

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 11 Jun 2021 15:16:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Thea Marie Cordero	17 Mar 2021 14:03:33
	(b) (4)	

**US3862099**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 11 Jun 2021 15:16:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'I'	System	17 Mar 2021 14:03:33

US3862099

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:16:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	25 Mar 2021 21:08:21
	(b) (4)	

US3862099

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:16:15

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '25 Mar 2021'	Chanei Henry (b) (4)	25 Mar 2021 21:08:21
	(b) (4)	

US3862099

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 11 Jun 2021 15:16:15

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Clinic (Clinic)'	Chanei Henry (b) (4)	25 Mar 2021 21:08:21
	(b) (4)	

**US3862099**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 11 Jun 2021 15:16:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'OLD57'	System	25 Mar 2021 21:08:21

US3862099

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	25 Mar 2021 21:11:24
	(b) (4)	

US3862099

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '25 Mar 2021'	Chanei Henry (b) (4)	25 Mar 2021 21:11:24
	(b) (4)	

US3862099

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '14:57'	Chanei Henry (b) (4)	25 Mar 2021 21:11:24
	(b) (4)	

US3862099

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered '25 Mar 2021 14:57'	System	25 Mar 2021 21:11:24

US3862099

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '97.7' F	Chanei Henry (b) (4)	25 Mar 2021 21:11:24
	(b) (4)	

US3862099

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Other (Other)'	Chanei Henry (b) (4)	25 Mar 2021 21:11:24
	(b) (4)	

US3862099

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'temporal'	Chanei Henry (b) (4)	25 Mar 2021 21:11:24
	(b) (4)	

US3862099

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '62'	Chanei Henry (b) (4)	25 Mar 2021 21:11:24
	(b) (4)	

US3862099

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'bpm'	System	25 Mar 2021 21:11:24

US3862099

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '15'	Chanei Henry (b) (4)	25 Mar 2021 21:11:24
	(b) (4)	

US3862099

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'breaths/min'	System	25 Mar 2021 21:11:24

US3862099

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '111'	Chanei Henry (b) (4)	25 Mar 2021 21:11:24
	(b) (4)	

US3862099

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'mmHg'	System	25 Mar 2021 21:11:24

US3862099

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '62'	Chanei Henry (b) (4)	25 Mar 2021 21:11:24
	(b) (4)	

**US3862099**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 11 Jun 2021 15:16:15**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered 'mmHg'	System	25 Mar 2021 21:11:24

US3862099

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52

US3862099

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 11 Jun 2021 15:16:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52

US3862099

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:16:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	25 Mar 2021 21:11:33
	(b) (4)	

US3862099

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 11 Jun 2021 15:16:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '25 Mar 2021'	Chanei Henry (b) (4)	25 Mar 2021 21:11:33
	(b) (4)	

US3862099

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:16:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Chanei Henry (b) (4)	25 Mar 2021 21:11:45
	(b) (4)	

US3862099

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:16:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '25 Mar 2021'	Chanei Henry (b) (4)	25 Mar 2021 21:11:45
	(b) (4)	

US3862099

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 11 Jun 2021 15:16:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '15:10'	Chanei Henry (b) (4)	25 Mar 2021 21:11:45
	(b) (4)	

**US3862099**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 11 Jun 2021 15:16:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 01:44:52
User entered '25 Mar 2021 15:10'	System	25 Mar 2021 21:11:45

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 11 Jun 2021 15:16:15**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:04:40
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:35
User entered 'Yes (Y)'	Sandra Francisco (b) (4) (b) (4)	19 Oct 2020 22:03:31

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09

US3862099

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:16:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Tinnitus, LLT: Ear ringing - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 23:49:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 23:49:35
Data point term sent to Coder	System	19 Oct 2020 22:05:29
User entered 'ringing in right ear'	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47

US3862099

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:16:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered 'No (N)' reason for change: New Information	Carrie Kibler (b) (4)	28 Oct 2020 20:50:40
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered 'No (N)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	19 Oct 2020 22:04:47

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered 'No (N)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	19 Oct 2020 22:04:47

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered '12 Oct 2020'	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered empty.	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User entered empty.	System	19 Oct 2020 22:04:47

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered 'No (N)' reason for change: New Information	Carrie Kibler (b) (4)	28 Oct 2020 20:50:40
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47

US3862099

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:16:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered '19 Oct 2020' reason for change: New Information	Carrie Kibler (b) (4)	28 Oct 2020 20:50:40
User entered empty.	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered empty.	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User entered empty.	System	19 Oct 2020 22:04:47

US3862099

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:16:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: Data Entry Error	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:50:40
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Sandra Francisco (b) (4)	19 Oct 2020 22:04:47
	(b) (4)	

US3862099

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:16:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Oct 2020 20:50:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 20:50:40
User entered 'No (N)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	28 Oct 2020 20:50:40
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty; reason for change Data Entry Error	System	19 Oct 2020 22:05:22
User entered 'No (N)'	Sandra Francisco (b) (4)	19 Oct 2020 22:05:22
	(b) (4)	
	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47
	(b) (4)	

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered '0'	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered '0'	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered '0'	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47

US3862099

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:16:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered empty.	(b) (4)	19 Oct 2020 22:04:47
	Sandra Francisco (b) (4)	
	(b) (4)	

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered empty.	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered empty.	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered empty.	(b) (4)	19 Oct 2020 22:04:47
	Sandra Francisco (b) (4)	
	(b) (4)	

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered '0'	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered '0'	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered '0'	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47

US3862099

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:16:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Oct 2020 20:50:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 20:50:40
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	28 Oct 2020 20:50:40
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Oct 2020 22:04:47
User entered empty.	System	19 Oct 2020 22:04:47
	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:16:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Oct 2020 20:50:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 20:50:40
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	28 Oct 2020 20:50:40
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Oct 2020 22:04:47
User entered empty.	System	19 Oct 2020 22:04:47
	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47
	(b) (4)	

US3862099

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:16:15

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Oct 2020 20:50:40
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 20:50:40
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	28 Oct 2020 20:50:40
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Oct 2020 22:04:47
User entered empty.	System	19 Oct 2020 22:04:47
	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47
	(b) (4)	

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered 'I'	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered '0'	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered '0'	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47

US3862099

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:16:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Carrie Kibler (b) (4)	28 Oct 2020 20:50:40
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered empty.	(b) (4) Sandra Francisco (b) (4)	19 Oct 2020 22:04:47

US3862099

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 11 Jun 2021 15:16:15

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered 'Subject experienced intermittent ringing in his right ear. The ringing subsided on October 19th without any interventions, medications, or doctor follow-up.' reason for change: New Information	Carrie Kibler (b) (4)	28 Oct 2020 20:52:58
User entered empty.	Sandra Francisco (b) (4)	19 Oct 2020 22:04:47

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User entered '0'	System	19 Oct 2020 22:04:47

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09
User entered '0'	System	28 Oct 2020 20:50:40
User entered '1'	System	19 Oct 2020 22:04:47

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:09

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02

US3862099

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:16:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache unilateral - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 09:21:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	20 Oct 2020 09:21:34
Data point term sent to Coder	System	19 Oct 2020 22:06:31
User entered 'superficial pain on right frontal to temporal region of head'	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered 'No (N)'	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered 'No (N)'	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered 'No (N)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	19 Oct 2020 22:06:19

US3862099

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:16:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered '19 Oct 2020'	(b) (4) Sandra Francisco (b) (4) (b) (4)	19 Oct 2020 22:06:19

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered empty.	(b) (4) Sandra Francisco (b) (4) (b) (4)	19 Oct 2020 22:06:19

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User entered empty.	System	19 Oct 2020 22:06:19

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered 'No (N)' reason for change: New Information	Carrie Kibler (b) (4)	28 Oct 2020 21:04:20
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19

US3862099

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:16:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	28 Oct 2020 21:07:51
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	28 Oct 2020 21:07:51
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	28 Oct 2020 21:04:20
User entered '19 Oct 2020' reason for change: New Information	Carrie Kibler (b) (4)	28 Oct 2020 21:04:20
User entered empty.	(b) (4)	
	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19
	(b) (4)	

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered empty.	(b) (4)	19 Oct 2020 22:06:19

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User entered empty.	System	19 Oct 2020 22:06:19

US3862099

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:16:15

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered 'Grade 1/Mild (Grade 1/Mild)' reason for change: New Information	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 21:04:20
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Sandra Francisco (b) (4)	19 Oct 2020 22:06:19

US3862099

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:16:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Oct 2020 21:03:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 21:03:48
User entered 'No (N)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	28 Oct 2020 21:03:48
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Oct 2020 22:06:19
User entered empty.	System	19 Oct 2020 22:06:19
	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19
	(b) (4)	

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered '0'	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered '0'	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered '0'	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19

US3862099

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:16:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered empty.	(b) (4) Sandra Francisco (b) (4) (b) (4)	19 Oct 2020 22:06:19

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered empty.	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered empty.	(b) (4) Sandra Francisco (b) (4) (b) (4)	19 Oct 2020 22:06:19

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered empty.	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered '0'	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered '0'	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered '0'	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19

US3862099

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:16:15

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Oct 2020 21:03:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 21:03:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	28 Oct 2020 21:03:48
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Oct 2020 22:06:19
User entered empty.	System	19 Oct 2020 22:06:19
	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:16:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Oct 2020 21:03:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 21:03:48
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	28 Oct 2020 21:03:48
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Oct 2020 22:06:19
User entered empty.	System	19 Oct 2020 22:06:19
	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:16:15

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	28 Oct 2020 21:03:48
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Oct 2020 21:03:48
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	28 Oct 2020 21:03:48
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	19 Oct 2020 22:06:19
User entered empty.	System	19 Oct 2020 22:06:19
	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:16:15

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	28 Oct 2020 21:03:51
User entered '0' reason for change: Data Entry Error	Carrie Kibler (b) (4)	28 Oct 2020 21:03:51
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	(b) (4)	19 Oct 2020 22:06:19
User entered '1'	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:16:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered 'I'	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered '0'	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 11 Jun 2021 15:16:15

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Carrie Kibler (b) (4)	28 Oct 2020 21:07:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4)	
	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19
	(b) (4)	

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered empty.	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered empty.	Sandra Francisco (b) (4)	19 Oct 2020 22:06:19

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User entered '0'	System	28 Oct 2020 21:03:48

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02
User entered '0'	System	19 Oct 2020 22:06:19

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 05:24:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:16:15

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:45:36
Reviewed for Safety.		18 Mar 2021 15:04:14
User entered 'USA-US121-2021-mRNA-1273-P301000006'	System	18 Mar 2021 15:04:09
User entered 'New'	(b) (4), (b) (6)	18 Mar 2021 15:04:09

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:16:15

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:00:02
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Urinary tract lithiasis (excl renal), PT: Ureterolithiasis, LLT: Ureteral calculus - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 07:02:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 07:02:29
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:22
Data point term sent to Coder	System	27 Mar 2021 00:25:11
User entered 'LEFT PROXIMAL AND DISTAL URETERAL CALCULI' reason for change: New Information	Thea Marie Cordero (b) (4)	27 Mar 2021 00:24:45
Data point term sent to Coder	System	27 Mar 2021 00:22:11
DataPoint Un-verified.	Thea Marie Cordero (b) (4)	27 Mar 2021 00:22:01
Coding entries removed.	Thea Marie Cordero (b) (4)	27 Mar 2021 00:22:01
Signature has been broken.	Thea Marie Cordero (b) (4)	27 Mar 2021 00:22:01
User entered 'NONOBSTRUCTING LEFT NEPHROLITHIASIS' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	27 Mar 2021 00:22:01
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:45:37
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 18:52:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Mar 2021 18:52:48
Data point term sent to Coder	System	17 Mar 2021 18:51:44
User entered 'NEPHROLITHIASIS'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:51:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:45:39
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:51:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:45:40
User entered 'No (N)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:51:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:45:42
User entered 'No (N)'	Thea Marie Cordero	17 Mar 2021 18:51:07
	(b) (4)	

US3862099

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:16:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'As per medical records, subject started showing symptoms from 22Feb2021. Please verify and reconcile' answered with 'That is correct. Another AE will be created for Left flank pain, hematuria and dysuria - this is the date when the participant went to ER for acute left pain due to left proximal and distal ureteral calculi' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 21:42:37
User opened query 'As per medical records, subject started showing symptoms from 22Feb2021. Please verify and reconcile' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:50:18
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:43:02
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:45:44
User entered '13 Mar 2021'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:51:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:45:46
User entered empty.	Thea Marie Cordero (b) (4)	17 Mar 2021 18:51:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 18:51:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:59:01
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
Signature has been broken.	(b) (4)	27 Mar 2021 00:22:01
User entered 'No (N)' reason for change: New Information	Thea Marie Cordero	27 Mar 2021 00:22:01
User signature succeeded.	(b) (4)	22 Mar 2021 15:15:31
User entered 'Yes (Y)'	Thea Marie Cordero	17 Mar 2021 18:51:07
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:16:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:59:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	(b) (4)	27 Mar 2021 00:24:45
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	27 Mar 2021 00:24:45
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	27 Mar 2021 00:24:45
DataPoint Un-verified.	Thea Marie Cordero	27 Mar 2021 00:24:45
Signature has been broken.	(b) (4)	27 Mar 2021 00:24:45
User entered '14 Mar 2021' reason for change: Data Entry Error	Thea Marie Cordero	27 Mar 2021 00:24:45
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	(b) (4)	27 Mar 2021 00:22:01
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	27 Mar 2021 00:22:01
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4)	18 Mar 2021 17:45:49
User entered empty.	(b) (4), (b) (6)	
	Thea Marie Cordero	17 Mar 2021 18:51:07
	(b) (4)	

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4)	18 Mar 2021 17:45:51
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 18:51:07
	Thea Marie Cordero	
	(b) (4)	

US3862099

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:16:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:16:10
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 20:43:35
User entered empty.	System	17 Mar 2021 18:51:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:45:52
User entered 'Grade 3/Severe (Grade 3/Severe)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:51:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:45:54
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:51:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:45:56
User entered '0'	Thea Marie Cordero	17 Mar 2021 18:51:07
	(b) (4)	

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:46:00
User entered '0'	Thea Marie Cordero	17 Mar 2021 18:51:07
	(b) (4)	

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:45:58
User entered 'I'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:51:07

US3862099

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:16:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:59:14
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
DataPoint Un-verified.	(b) (4)	27 Mar 2021 00:19:00
Signature has been broken.	Thea Marie Cordero	27 Mar 2021 00:19:00
User entered '14 Mar 2021' reason for change: Data Entry Error	(b) (4)	27 Mar 2021 00:19:00
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:46:03
User entered '13 Mar 2021'	Thea Marie Cordero	17 Mar 2021 18:51:07
	(b) (4)	

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

**Hospital Discharge Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:59:17
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered '15 Mar 2021'	(b) (4)	17 Mar 2021 18:51:07
	Thea Marie Cordero	
	(b) (4)	

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:59:19
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered 'No (N)'	(b) (4)	17 Mar 2021 18:51:07
	Thea Marie Cordero	
	(b) (4)	

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:46:10
User entered empty.	Thea Marie Cordero (b) (4)	17 Mar 2021 18:51:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:46:15
User entered '0'	Thea Marie Cordero	17 Mar 2021 18:51:07
	(b) (4)	

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:46:12
User entered '0'	Thea Marie Cordero	17 Mar 2021 18:51:07
	(b) (4)	

US3862099

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:16:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:46:30
User entered '0'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:51:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:46:31
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:51:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:46:33
User entered 'Not Related (NOT RELATED)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:51:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:46:34
User entered 'Not Applicable (NOT APPLICABLE)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:51:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:46:38
User entered '0'	Thea Marie Cordero	17 Mar 2021 18:51:07
	(b) (4)	

US3862099

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:16:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 06:36:29
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Please review concomitant medication again. The medication recorded overlaps two SAE entries during the same timeframe and is documented as such.' (Site from DM).	Sandra Francisco (b) (4)	06 Apr 2021 01:29:35
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	04 Apr 2021 16:04:22
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:47:23
User entered 'I'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:51:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:47:25
User entered 'I'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:51:07

US3862099

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:16:15

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:02:50
Query 'As Per Source AE#03, Outcome is recorded as Not Recovered. Please verify and update as needed' canceled (Site from CRA).		16 Apr 2021 16:02:47
User opened query 'As Per Source AE#03, Outcome is recorded as Not Recovered. Please verify and update as needed' (Site from CRA).		16 Apr 2021 16:02:05
DataPoint Un-verified.		16 Apr 2021 16:01:09
DataPoint Verified.		16 Apr 2021 15:59:24
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		29 Mar 2021 16:54:05
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
	(b) (4)	
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'SEE NARRATIVE NOTE' (Site from Safety).	Thea Marie Cordero	27 Mar 2021 00:27:03
	(b) (4)	
Signature has been broken.	Thea Marie Cordero	27 Mar 2021 00:22:01
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Thea Marie Cordero	27 Mar 2021 00:22:01
	(b) (4)	
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 16:42:18
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 16:11:48

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:16:15

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'pending medical records.' (Site from Safety).	Carrie Kibler (b) (4) (b) (4)	24 Mar 2021 22:16:59
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 20:43:06
User signature succeeded.	Thea Marie Cordero (b) (4)	22 Mar 2021 15:15:31
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:51:07

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:59:27
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
User entered empty.	(b) (4)	17 Mar 2021 18:51:07
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:16:15

[Narrative](#)

Audit	User	Time (GMT)
User entered '13 MAR 2021: SUBJECT HAD SEVERE LEFT FLANK PAIN, WENT TO ER. CT RENAL STONE PROTOCOL DONE: LEFT PROXIMAL 10MM AND DISTAL 7MM URETERAL CALCULI CAUSING OBSTRUCTION AND NON-OBSTRUCTIVE 8 MM LEFT KIDNEY STONE, MILD LEFT HYDROURETERONEPHROSIS AND PERIURETERAL AND PERINEPHRIC FAT STRANDING, NON-OBSTRUCTING LEFT NEPHROLITHIASIS. UROLOGY CONSULT DONE, UNDERWENT CYSTOSCOPY, URETEROSCOPY, LASER LITHOTRIPSY WITH STONE REMOVAL AND URETERAL STENT PLACEMENT 15 MAR 2021: WAS DISCHARGED HOME WITH URETERAL STENT IN PLACED AND DISCHARGE MEDICATIONS. 22 MAR 2021: UROLOGIST APPOINTMENT FOR FOLLOW-UP AND PLAN FOR 8 MM KIDNEY STONE (LEFT NONOBSTRUCTING LEFT NEPHROLITHIASIS)' (WR#5445128)	System	11 Jun 2021 14:45:08
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 15:59:29
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 14:40:05
User closed query 'PV Query: please confirm is ureteral stent has been removed.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 14:40:01
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'SENT TODAY' (Site from Safety).	Thea Marie Cordero	06 Apr 2021 22:35:16
Query 'PV Query: please confirm is ureteral stent has been removed.' answered with 'URETERAL STENT STILL IN PLACED.' (Site from Safety).	Thea Marie Cordero	06 Apr 2021 22:19:06

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:16:15

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 19:34:38
User opened query 'PV Query: please confirm is ureteral stent has been removed.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 19:34:23
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 16:54:15
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)	29 Mar 2021 16:54:12
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 16:54:10
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'WILL BE SENT AFTER PATIENT IDENTIFIERS ARE REDACTED' (Site from Safety).	(b) (4) Thea Marie Cordero	27 Mar 2021 00:52:59
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'COVID 19 QUALITATIVE PCR TEST: NOT DETECTED' (Site from Safety).	Thea Marie Cordero (b) (4)	27 Mar 2021 00:52:42

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:16:15

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'DIAGNOSTIC TEST AND PROCEDURES: SEE NARRATIVE. LAB TEST: URINALYSIS: WBC 5 HPF, WBC 11 HPF, CBC WITH DIFFERENTIAL: WBC 8.3 K/UL, RBC 4.9 M/UL HGB 13.9 G/DL, NEUTROPHILS 79.1 %, LYMPHOCYTES 13.2 %, CMP: GLUCOSE 111 MG/DL, GFR 77 ML/MIN' (Site from Safety). User entered '13 MAR 2021: SUBJECT HAD SEVERE LEFT FLANK PAIN, WENT TO ER. CT RENAL STONE PROTOCOL DONE: LEFT PROXIMAL 10MM AND DISTAL 7MM URETERAL CALCULI CAUSING OBSTRUCTION AND NON-OBSTRUCTIVE 8 MM LEFT KIDNEY STONE, MILD LEFT HYDROURETERONEPHROSIS AND PERIURETERAL AND PERINEPHRIC FAT STRANDING, NON-OBSTRUCTING LEFT NEPHROLITHIASIS. UROLOGY CONSULT DONE, UNDERWENT CYSTOSCOPY, URETEROSCOPY, LASER LITHOTRIPSY WITH STONE REMOVAL AND URETERAL STENT PLACEMENT 15 MAR 2021: WAS DISCHARGED HOME WITH URETERAL STENT IN PLACED AND DISCHARGE MEDICATIONS. 22 MAR 2021: UROLOGIST APPOINTMENT FOR FOLLOW-UP AND PLAN FOR 8 MM KIDNEY STONE (LEFT NONOBSTRUCTING LEFT NEPHROLITHIASIS)' reason for change: New Information	Thea Marie Cordero (b) (4)	27 Mar 2021 00:52:16
	Thea Marie Cordero (b) (4)	27 Mar 2021 00:28:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:16:15

[Narrative](#)

Audit	User	Time (GMT)
User entered '13 MAR 2021: SUBJECT HAD SEVERE LEFT FLANK PAIN, WENT TO ER. CT RENAL STONE PROTOCOL DONE: LEFT PROXIMAL 10MM AND DISTAL 7MM URETERAL CALCULI CAUSING OBSTRUCTION AND NON-OBSTRUCTIVE 8 MM LEFT KIDNEY STONE, MILD LEFT HYDROURETERONEPHROSIS AND PERIURETERAL AND PERINEPHRIC FAT STRANDING, NON-OBSTRUCTING LEFT NEPHROLITHIASIS. UROLOGY CONSULT DONE, UNDERWENT CYSTOSCOPY, URETEROSCOPY, LASER LITHOTRIPSY WITH STONE REMOVAL AND URETERAL STENT PLACEMENT 15 MAR 2021: WAS DISCHARGED HOME WITH URETERAL STENT IN PLACED AND DISCHARGE MEDICATIONS.  22 MAR 2021: UROLOGIST APPOINTMENT FOR FOLLOW-UP AND PLAN FOR 8 MM KIDNEY STONE (LEFT NONOBSTRUCITNG LEFT NEPHROLITHIASIS)' reason for change: New Information DataPoint Un-verified.	Thea Marie Cordero (b) (4)	27 Mar 2021 00:28:07
Signature has been broken.	Thea Marie Cordero (b) (4)	27 Mar 2021 00:19:00

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:16:15

[Narrative](#)

Audit	User	Time (GMT)
User entered '13 MAR 2021: SUBJECT HAD SEVERE LEFT FLANK PAIN, WENT TO ER. CT RENAL STONE PROTOCOL DONE: LEFT PROXIMAL 10MM AND DISTAL 7MM URETERAL CALCULI CAUSING OBSTRUCTION AND NON-OBSTRUCTIVE 8 MM LEFT KIDNEY STONE, MILD LEFT HYDROURETERONEPHROSIS AND PERIURETERAL AND PERINEPHRIC FAT STRANDING, NON-OBSTRUCTING LEFT NEPHROLITHIASIS. UROLOGY CONSULT DONE, UNDERWENT CYSTOSCOPY, URETEROSCOPY, LASER LITHOTRIPSY WITH STONE REMOVAL AND URETERAL STENT PLACEMENT 15 MAR 2021: WAS DISCHARGED HOME WITH URETERAL STENT IN PLACED AND DISCHARGE MEDICATIONS.  22 MAR 2021: UROLOGIST APPOINTMENT FOR FOLLOW-UP AND PLAN FOR 8 MM KIDNEY STONE' reason for change: New Information	Thea Marie Cordero (b) (4)	27 Mar 2021 00:19:00
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 16:42:31
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)	25 Mar 2021 16:42:07
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 16:42:03
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 16:12:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:16:15

[Narrative](#)

Audit	User	Time (GMT)
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)	25 Mar 2021 16:11:57
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		25 Mar 2021 16:11:53
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 'pending medical records.' (Site from Safety).	Carrie Kibler (b) (4) (b) (4)	24 Mar 2021 22:17:04
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'pending medical records.' (Site from Safety).	Carrie Kibler (b) (4) (b) (4)	24 Mar 2021 22:17:02
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'pending medical records.' (Site from Safety).	Carrie Kibler (b) (4) (b) (4)	24 Mar 2021 22:14:48
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 20:43:22
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)	23 Mar 2021 20:43:15
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 20:42:55

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 11 Jun 2021 15:16:15

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:15:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:49:50
User entered '13 Mar 2021: Subject had severe left flank pain, went to ER. CT Scan of Abdomen and Pelvis showed 3 stones- 7mm, 8mm and 10 mm in the left kidney. 14 Mar 2021: Had laparoscopic surgery for removal of 7mm and 10 mm stones. Had placement of ureteral stent 15 Mar 2021: Was discharged home with ureteral stent in placed and discharge medications. 22 Mar 2021: Urologist appointment for follow-up and plan for 8 mm kidney stone'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:51:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Mar 2021 18:51:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Mar 2021 18:51:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Mar 2021 18:51:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:29
Reviewed for Safety.		07 Apr 2021 14:40:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'USA-US121-2021-mRNA-1273-P301000006'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 16:50:48

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:16:15

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:31
User coded data point as SOC: Renal and urinary disorders, HLGT: Urolithiasis, HLT: Renal lithiasis, PT: Nephrolithiasis, LLT: Nephrolithiasis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 08:58:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Mar 2021 08:58:33
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:22
Data point term sent to Coder	System	27 Mar 2021 01:17:13
User entered 'NON OBSTRUCTING LEFT NEPHROLITHIASIS'	Thea Marie Cordero (b) (4)	27 Mar 2021 00:34:01

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:33
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered 'Yes (Y)'	(b) (4)	27 Mar 2021 00:34:01
	Thea Marie Cordero	
	(b) (4)	

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:35
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered 'No (N)'	(b) (4)	27 Mar 2021 00:34:01
	Thea Marie Cordero	
	(b) (4)	

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered 'No (N)'	(b) (4)	27 Mar 2021 00:34:01
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:16:15

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:43:23
DataPoint Verified.		16 Apr 2021 16:03:38
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered '13 Mar 2021'	(b) (4)	
	Thea Marie Cordero	27 Mar 2021 00:34:01
	(b) (4)	

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered empty.	(b) (4)	27 Mar 2021 00:34:01
	Thea Marie Cordero	
	(b) (4)	

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Mar 2021 00:34:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:16:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
DataPoint Un-verified.	(b) (4)	20 Apr 2021 20:07:24
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 20:07:24
User entered 'No (N)' reason for change: Data Entry Error		20 Apr 2021 20:07:24
DataPoint Verified.		16 Apr 2021 16:03:47
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered 'Yes (Y)'	(b) (4)	27 Mar 2021 00:34:01
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:16:15

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4), (b) (6)	29 Apr 2021 15:52:23
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 16:13:58
DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 16:13:54
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered with 'Updated in EDC - correct date per source document, the admission was on 14 Apr 2021' (Site from System).	(b) (4), (b) (6)	20 Apr 2021 20:10:04
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	20 Apr 2021 20:07:24
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 20:07:24
Signature has been broken.		20 Apr 2021 20:07:24
User entered '11 Apr 2021' reason for change: Data Entry Error		20 Apr 2021 20:07:24
DataPoint Verified.		16 Apr 2021 16:03:52
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered empty.	(b) (4)	
	Thea Marie Cordero	27 Mar 2021 00:34:01
	(b) (4)	

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:54
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered empty.	(b) (4)	27 Mar 2021 00:34:01
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:16:15

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date of NON OBSTRUCTING LEFT NEPHROLITHIASIS (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	27 Apr 2021 23:17:10
User opened query 'PV Query: Please provide the event end date of NON OBSTRUCTING LEFT NEPHROLITHIASIS (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 19:28:47
User entered empty.	System	27 Mar 2021 00:34:01

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:55
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4)	27 Mar 2021 00:34:01
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:16:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:03:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	(b) (4)	27 Mar 2021 00:36:19
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	27 Mar 2021 00:34:01
User entered 'Yes (Y)'	Thea Marie Cordero	27 Mar 2021 00:34:01
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:00
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered '0'	(b) (4)	27 Mar 2021 00:34:01
	Thea Marie Cordero	
	(b) (4)	

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:03
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered '0'	(b) (4)	27 Mar 2021 00:34:01
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:16:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:05
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	27 Mar 2021 00:36:19
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		27 Mar 2021 00:36:19
User entered '1' reason for change: Data Entry Error	Thea Marie Cordero	27 Mar 2021 00:36:19
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	27 Mar 2021 00:34:01
User entered '0'	Thea Marie Cordero	27 Mar 2021 00:34:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:16:15

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User closed query 'As per Source, Hospital Admission date is recorded as 13MAR2021. Please verify and update as needed.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	27 Apr 2021 16:14:27
Query 'As per Source, Hospital Admission date is recorded as 13MAR2021. Please verify and update as needed.' answered with 'Updated in the EDC and Source Document' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 20:11:49
User entered '14 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 20:10:47
Signature has been broken.		20 Apr 2021 20:06:09
User entered '13 Mar 2021' reason for change: Data Entry Error		20 Apr 2021 20:06:09
User opened query 'As per Source, Hospital Admission date is recorded as 13MAR2021. Please verify and update as needed.' (Site from CRA).		16 Apr 2021 16:07:15
DataPoint Un-verified.		16 Apr 2021 16:04:15
DataPoint Verified.		16 Apr 2021 16:04:07
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:22
User entered '14 Mar 2021'	Thea Marie Cordero (b) (4)	27 Mar 2021 00:34:01

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:19
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered '15 Mar 2021'	(b) (4)	27 Mar 2021 00:34:01
	Thea Marie Cordero	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:21
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered 'No (N)'	(b) (4)	27 Mar 2021 00:34:01
	Thea Marie Cordero	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:24
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered empty.	(b) (4)	27 Mar 2021 00:34:01
	Thea Marie Cordero	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:26
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered '0'	(b) (4)	27 Mar 2021 00:34:01
	Thea Marie Cordero	
	(b) (4)	

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:28
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered '0'	(b) (4)	27 Mar 2021 00:34:01
	Thea Marie Cordero	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:29
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered '0'	(b) (4)	27 Mar 2021 00:34:01
	Thea Marie Cordero	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:32
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered 'Not Related (NOT RELATED)'	(b) (4)	27 Mar 2021 00:34:01
	Thea Marie Cordero	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:35
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered 'Not Related (NOT RELATED)'	(b) (4)	27 Mar 2021 00:34:01
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:16:15

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User closed query 'PV Query: As the last dose of [study drug] was given on 12 Feb 2021, please update the action taken with [study drug] from none to not applicable for event, NON OBSTRUCTING LEFT NEPHROLITHIASIS.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:52:57
Query 'PV Query: As the last dose of [study drug] was given on 12 Feb 2021, please update the action taken with [study drug] from none to not applicable for event, NON OBSTRUCTING LEFT NEPHROLITHIASIS.' answered with 'Updated in the EDC and Source Document' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 20:12:15
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 20:07:24
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: New Information		20 Apr 2021 20:07:24
User opened query 'PV Query: As the last dose of [study drug] was given on 12 Feb 2021, please update the action taken with [study drug] from none to not applicable for event, NON OBSTRUCTING LEFT NEPHROLITHIASIS.' (Site from Safety).		14 Apr 2021 13:31:05
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:22
User entered 'None (NONE)'	Thea Marie Cordero (b) (4)	27 Mar 2021 00:34:01

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:55
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered '0'	(b) (4)	27 Mar 2021 00:34:01
	Thea Marie Cordero	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:56
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered 'I'	(b) (4)	27 Mar 2021 00:34:01
	Thea Marie Cordero	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:04:58
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered '1' reason for change: New Information	(b) (4)	27 Mar 2021 00:35:47
User entered '0'	Thea Marie Cordero	27 Mar 2021 00:34:01
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:16:15

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User closed query 'PV Query: Please provide the final event outcome, of the event NON OBSTRUCTING LEFT NEPHROLITHIASIS,when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety). Query 'PV Query: Please provide the final event outcome, of the event NON OBSTRUCTING LEFT NEPHROLITHIASIS,when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'UPDATED IN SOURCE DOCUMENT AND EDC' (Site from Safety). DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	26 Apr 2021 13:21:22
	Thea Marie Cordero (b) (4)	23 Apr 2021 17:34:58
	(b) (4), (b) (6)	20 Apr 2021 20:11:12
Signature has been broken.		20 Apr 2021 20:11:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information		20 Apr 2021 20:11:12
DataPoint Verified.		16 Apr 2021 16:05:01
User opened query 'PV Query: Please provide the final event outcome, of the event NON OBSTRUCTING LEFT NEPHROLITHIASIS,when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		14 Apr 2021 13:31:15
User closed query 'PV Query: Please provide the final event outcome, of the event NON OBSTRUCTING LEFT NEPHROLITHIASIS,when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 14:40:26

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Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:16:15

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, of the event NON OBSTRUCTING LEFT NEPHROLITHIASIS,when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'PLANNED LAPAROSCOPIC SURGERY WILL BE ON 09 APR 2021' (Site from Safety).	Thea Marie Cordero (b) (4)	06 Apr 2021 22:21:23
User opened query 'PV Query: Please provide the final event outcome, of the event NON OBSTRUCTING LEFT NEPHROLITHIASIS,when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 19:27:57
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:22:22
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Thea Marie Cordero (b) (4)	27 Mar 2021 00:34:01

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:05:11
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:22:22
User entered empty.	(b) (4)	27 Mar 2021 00:34:01
	Thea Marie Cordero	
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:16:15

[Narrative](#)

Audit	User	Time (GMT)
User entered '13 MAR 2021: SUBJECT HAD SEVERE LEFT FLANK PAIN, WENT TO ER. CT RENAL STONE PROTOCOL DONE: LEFT PROXIMAL 10MM AND DISTAL 7MM URETERAL CALCULI CAUSING OBSTRUCTION AND NON-OBSTRUCTIVE 8 MM LEFT KIDNEY STONE, MILD LEFT HYDROURETERONEPHROSIS AND PERIURETERAL AND PERINEPHRIC FAT STRANDING, NON-OBSTRUCTING LEFT NEPHROLITHIASIS. UROLOGY CONSULT DONE, UNDERWENT CYSTOSCOPY, URETEROSCOPY, LASER LITHOTRIPSY WITH STONE REMOVAL AND URETERAL STENT PLACEMENT 15 MAR 2021: WAS DISCHARGED HOME WITH URETERAL STENT IN PLACED AND DISCHARGE MEDICATIONS. 22 MAR 2021: UROLOGIST APPOINTMENT FOR FOLLOW-UP AND PLAN FOR 8 MM KIDNEY STONE 20 APR 2021. NONOBSTRUCTIVE LEFT RENAL CALCULUS REMOVED ON 11 APR 2021. MEDICAL RECORD PENDING. 19 APR 2021 URETHRAL STENT REMOVED - MEDICAL RECORD PENDING' (WR#5445128)	System	11 Jun 2021 14:45:08
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	28 Apr 2021 22:04:03







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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 11 Jun 2021 15:16:15

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6)	05 Apr 2021 19:30:08
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	Thea Marie Cordero	29 Mar 2021 14:22:22
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	(b) (4)	27 Mar 2021 00:35:47
User entered '13 MAR 2021: SUBJECT HAD SEVERE LEFT FLANK PAIN, WENT TO ER. CT RENAL STONE PROTOCOL DONE: LEFT PROXIMAL 10MM AND DISTAL 7MM URETERAL CALCULI CAUSING OBSTRUCTION AND NON-OBSTRUCTIVE 8 MM LEFT KIDNEY STONE, MILD LEFT HYDROURETERONEPHROSIS AND PERIURETERAL AND PERINEPHRIC FAT STRANDING, NON-OBSTRUCTING LEFT NEPHROLITHIASIS. UROLOGY CONSULT DONE, UNDERWENT CYSTOSCOPY, URETEROSCOPY, LASER LITHOTRIPSY WITH STONE REMOVAL AND URETERAL STENT PLACEMENT 15 MAR 2021: WAS DISCHARGED HOME WITH URETERAL STENT IN PLACED AND DISCHARGE MEDICATIONS. 22 MAR 2021: UROLOGIST APPOINTMENT FOR FOLLOW-UP AND PLAN FOR 8 MM KIDNEY STONE' reason for change: Data Entry Error	System	27 Mar 2021 00:35:47
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	Thea Marie Cordero	27 Mar 2021 00:34:01
User entered empty.	(b) (4)	27 Mar 2021 00:34:01

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**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Mar 2021 00:34:01

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Mar 2021 00:34:01

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Mar 2021 00:34:01

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:53:23
User entered 'USA-US121-2021-mRNA-1273-P301000006'		21 Apr 2021 13:53:16

US3862099

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:16:15

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Flank pain, LLT: Flank pain - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 21:53:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 21:53:40
	(b) (4)	
Data point term sent to Coder	System	20 Apr 2021 21:52:55
User entered 'LEFT FLANK PAIN'	(b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '30 Dec 2020'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 21:52:07

US3862099

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:16:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	20 Apr 2021 21:52:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	20 Apr 2021 21:52:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 21:52:34
User opened query 'Data is required. Please complete.' (Site from System).	System	20 Apr 2021 21:52:07
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '11 Apr 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

US3862099

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:16:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
	(b) (4)	
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	20 Apr 2021 21:52:34
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	20 Apr 2021 21:52:07
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

US3862099

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 11 Jun 2021 15:16:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
	(b) (4)	
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	20 Apr 2021 21:52:34
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		20 Apr 2021 21:52:34
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 21:52:34
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	20 Apr 2021 21:52:07
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '14 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '15 Mar 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '1'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '1'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'SEE COMMENTS FOR LEFT PROXIMAL AND DISTAL URETHRAL CALCULI AE'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Apr 2021 21:52:07

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50

US3862099

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:16:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Urinary abnormalities, PT: Haematuria, LLT: Hematuria - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 22:25:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 22:25:47
Data point term sent to Coder	System	20 Apr 2021 22:24:29
User entered 'GROSS HEMATURIA'	(b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

US3862099

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:16:15

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '4 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User entered empty.	System	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

**If not Ongoing, end date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User entered empty.	System	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

US3862099

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:16:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

US3862099

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:16:15

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

US3862099

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:16:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

US3862099

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 11 Jun 2021 15:16:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User entered '0'	System	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50
User entered 'I'	System	20 Apr 2021 22:24:12

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:58:50

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44

US3862099

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Jun 2021 15:16:15

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Dysuria, LLT: Difficulty voiding - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 08:39:24
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	21 Apr 2021 08:39:24
Data point term sent to Coder	System	20 Apr 2021 22:25:31
User entered 'VOIDING DIFFICULTLY'	(b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '4 Jan 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User entered empty.	System	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

US3862099

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Jun 2021 15:16:15

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User entered empty.	System	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

US3862099

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 11 Jun 2021 15:16:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

**Hospital Discharge Date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'I'	(b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User entered '0'	System	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44
User entered 'I'	System	20 Apr 2021 22:25:10

**US3862099**

**Folder: Adverse Events**

**Form: Adverse Events (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 02:57:44

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Jun 2021 15:16:15

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:04:40
User closed query 'As per Medical records from Hospitalization, Subject was given Zofran-ODT,ZOFRAN inj and NARCAN. Please verify and update source and EDC as needed.' (Site from CRA).		27 Apr 2021 16:16:11
Query 'As per Medical records from Hospitalization, Subject was given Zofran-ODT,ZOFRAN inj and NARCAN. Please verify and update source and EDC as needed.' answered with 'ZOFRAN ODT, ZOFRAN IV, AND NARCAN IV WERE ORDERED AS STANDING PRN ORDERS. AS REFLECTED IN MEDICAL RECORDS , THEY WERE NOT ADMINISTERED' (Site from CRA).	Thea Marie Cordero (b) (4)	20 Apr 2021 23:12:32
User opened query 'As per Medical records from Hospitalization, Subject was given Zofran-ODT,ZOFRAN inj and NARCAN. Please verify and update source and EDC as needed.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 18:30:19
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:28:17
DataPoint Un-verified.		16 Apr 2021 18:28:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:53:11
User closed query 'Per CDM: 'Was any medication taken today for pain and fever?' is recorded 'Yes' on 04 Oct 2020 at 12:00. Site response on e-Diary form (Dose Temp Log Line 8) indicates medication was updated in ConMed. However, there is no data that supports this, that is recorded on ConMed form. Please reconcile data on e-Diary form (Dose Temp Log Line 8) with other applicable forms: ConMed. Please refer to protocol section 6.4 which includes specific details for all Prior and Concomitant Medications and Therapies Reporting. Thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 04:20:04

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 11 Jun 2021 15:16:15

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Query 'Per CDM: 'Was any medication taken today for pain and fever?' is recorded 'Yes' on 04 Oct 2020 at 12:00. Site response on e-Diary form (Dose Temp Log Line 8) indicates medication was updated in ConMed. However, there is no data that supports this, that is recorded on ConMed form. Please reconcile data on e-Diary form (Dose Temp Log Line 8) with other applicable forms: ConMed. Please refer to protocol section 6.4 which includes specific details for all Prior and Concomitant Medications and Therapies Reporting. Thank you. ' answered with 'data entered' (Site from DM).	Trent Davis (b) (4) (b) (4)	16 Dec 2020 19:17:31
User opened query 'Per CDM: 'Was any medication taken today for pain and fever?' is recorded 'Yes' on 04 Oct 2020 at 12:00. Site response on e-Diary form (Dose Temp Log Line 8) indicates medication was updated in ConMed. However, there is no data that supports this, that is recorded on ConMed form. Please reconcile data on e-Diary form (Dose Temp Log Line 8) with other applicable forms: ConMed. Please refer to protocol section 6.4 which includes specific details for all Prior and Concomitant Medications and Therapies Reporting. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4)	03 Nov 2020 14:02:44
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:21:20

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: COBICISTAT;DARUNAVIR ETHANOLATE, PRODUCTSYNONYM: PREZCOBIX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 21:24:35
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 21:24:35
	(b) (4)	
Data point term sent to Coder	System	31 Aug 2020 21:24:02
User entered 'prezcobix'	Carrie Kibler (b) (4)	31 Aug 2020 21:23:26
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:16:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	31 Aug 2020 21:23:26
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'hiv'	Carrie Kibler (b) (4)	31 Aug 2020 21:23:26
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '800/150'	Carrie Kibler (b) (4)	31 Aug 2020 21:23:26
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:16:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'mg (mg)'	Carrie Kibler (b) (4)	31 Aug 2020 21:23:26
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Jun 2021 15:16:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	31 Aug 2020 21:23:26
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 11 Jun 2021 15:16:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'once daily (QD)'	Carrie Kibler (b) (4)	31 Aug 2020 21:23:26
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Jun 2021 15:16:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	31 Aug 2020 21:23:26
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	31 Aug 2020 21:23:26
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Jun 2021 15:16:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	31 Aug 2020 21:23:26
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'un Dec 2018'	Carrie Kibler (b) (4)	31 Aug 2020 21:23:26
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	31 Aug 2020 21:23:26
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	31 Aug 2020 21:23:26
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Jun 2021 15:16:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	31 Aug 2020 21:23:26
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	31 Aug 2020 21:23:26
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:23:26

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:23:26

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 21:23:26

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: DORAVIRINE, PRODUCTSYNONYM: PIFELTRO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 21:25:37
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 21:25:37
	(b) (4)	
Data point term sent to Coder	System	31 Aug 2020 21:25:05
User entered 'pifeltro'	Carrie Kibler (b) (4)	31 Aug 2020 21:24:52
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:16:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	31 Aug 2020 21:24:52
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'hiv'	Carrie Kibler (b) (4)	31 Aug 2020 21:24:52
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '100'	Carrie Kibler (b) (4)	31 Aug 2020 21:24:52
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:16:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'mg (mg)'	Carrie Kibler (b) (4)	31 Aug 2020 21:24:52
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Jun 2021 15:16:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	31 Aug 2020 21:24:52
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:16:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'once daily (QD)'	Carrie Kibler (b) (4)	31 Aug 2020 21:24:52
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Jun 2021 15:16:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	31 Aug 2020 21:24:52
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	31 Aug 2020 21:24:52
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Jun 2021 15:16:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	31 Aug 2020 21:24:52
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:16:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'un Dec 2018'	Carrie Kibler (b) (4)	31 Aug 2020 21:24:52
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	31 Aug 2020 21:24:52
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 11 Jun 2021 15:16:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	31 Aug 2020 21:24:52
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Jun 2021 15:16:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	31 Aug 2020 21:24:52
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	31 Aug 2020 21:24:52
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:24:52

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:24:52

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 21:24:52

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDE AND NUCLEOTIDE REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ENTECAVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 05:47:49
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 05:47:49
	(b) (4)	
Data point term sent to Coder	System	31 Aug 2020 21:26:08
User entered 'entecavir'	Carrie Kibler (b) (4)	31 Aug 2020 21:25:50
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:16:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	31 Aug 2020 21:25:50
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'hepatitis b'	Carrie Kibler (b) (4)	31 Aug 2020 21:25:50
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:16:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '1'	Carrie Kibler (b) (4)	31 Aug 2020 21:25:50
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:16:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'mg (mg)'	Carrie Kibler (b) (4)	31 Aug 2020 21:25:50
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Jun 2021 15:16:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	31 Aug 2020 21:25:50
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:16:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'once daily (QD)'	Carrie Kibler (b) (4)	31 Aug 2020 21:25:50
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Jun 2021 15:16:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	31 Aug 2020 21:25:50
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	31 Aug 2020 21:25:50
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Jun 2021 15:16:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	31 Aug 2020 21:25:50
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 11 Jun 2021 15:16:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'un Feb 2005'	Carrie Kibler (b) (4)	31 Aug 2020 21:25:50
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	31 Aug 2020 21:25:50
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	31 Aug 2020 21:25:50
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Jun 2021 15:16:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	31 Aug 2020 21:25:50
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	31 Aug 2020 21:25:50
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:25:50

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Aug 2020 21:25:50

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Aug 2020 21:25:50

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:07
DataPoint Verified.		16 Apr 2021 16:16:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Feb 2021 17:26:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 17:26:51
Data point term sent to Coder Coding entries removed.	System Carrie Kibler (b) (4) (b) (4)	19 Feb 2021 17:26:22 19 Feb 2021 17:26:00
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:07:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:07:56
Data point term sent to Coder Data point term sent to Coder Coding entries removed.	System System Shetel Anassi (b) (4) (b) (4)	26 Oct 2020 19:38:44 26 Oct 2020 19:37:40 26 Oct 2020 19:36:44

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:29:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 21:29:42
Data point term sent to Coder	System	31 Aug 2020 21:28:13
User entered 'ibuprofen'	Carrie Kibler (b) (4) (b) (4)	31 Aug 2020 21:27:18

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:16:15

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 16:17:08
DataPoint Verified.		16 Apr 2021 16:16:58
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	26 Oct 2020 19:37:54
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Shetel Anassi (b) (4)	26 Oct 2020 19:36:51
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	31 Aug 2020 21:27:18
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM: Site response noted for the previous query. However, there is no MH recorded in the Medical history page. Please review and update the Medical history eCRF as applicable. Thankyou.' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 14:39:48
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
Query 'Per CDM: Site response noted for the previous query. However, there is no MH recorded in the Medical history page. Please review and update the Medical history eCRF as applicable. Thankyou.' answered with 'medical history in EDC and source doc updated ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:12:59
User opened query 'Per CDM: Site response noted for the previous query. However, there is no MH recorded in the Medical history page. Please review and update the Medical history eCRF as applicable. Thankyou.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 12:31:32
User closed query 'Per DM CLR: Please review if this Conmed was given for the AE #1. If so, please note "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Kindly review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 12:27:59
Query 'Per DM CLR: Please review if this Conmed was given for the AE #1. If so, please note "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Kindly review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' answered with 'subject takes ibuprofen for general aches and pains. reported upon enrollment.' (Site from DM).	Carrie Kibler (b) (4) (b) (4)	19 Feb 2021 17:26:52
User entered 'general pain' reason for change: Data Entry Error	Carrie Kibler (b) (4) (b) (4)	19 Feb 2021 17:26:00

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this Conmed was given for the AE #1. If so, please note "Other Action Taken" on the AE eCRF does not reflect that a CM was given. Kindly review and reconcile CM and AE eCRF as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 06:56:08
User closed query 'Per DM CLR : Please note there is no MH condition or AE that matches this CM indication. Please review the CM use and add a medical condition and all applicable details to appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 13:04:11
Query 'Per DM CLR : Please note there is no MH condition or AE that matches this CM indication. Please review the CM use and add a medical condition and all applicable details to appropriate MH or AE eCRF.' answered with 'AE on file indicates medication is appropriate ' (Site from DM).	Shetel Anassi (b) (4)	26 Oct 2020 19:38:32
User entered 'PAIN for ear ringing' reason for change: Data Entry Error	Shetel Anassi (b) (4)	26 Oct 2020 19:37:54
User entered 'Prophylaxis for PAIN' reason for change: Data Entry Error	Shetel Anassi (b) (4)	26 Oct 2020 19:36:44
User opened query 'Per DM CLR : Please note there is no MH condition or AE that matches this CM indication. Please review the CM use and add a medical condition and all applicable details to appropriate MH or AE eCRF.' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 19:26:15
User entered 'pain'	Carrie Kibler (b) (4)	31 Aug 2020 21:27:18

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '400'	Carrie Kibler (b) (4)	31 Aug 2020 21:27:18
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:16:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'mg (mg)'	Carrie Kibler (b) (4)	31 Aug 2020 21:27:18
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Jun 2021 15:16:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	31 Aug 2020 21:27:18
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:16:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'as needed (PRN)'	Carrie Kibler (b) (4)	31 Aug 2020 21:27:18
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Jun 2021 15:16:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	31 Aug 2020 21:27:18
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Oral (ORAL)'	Carrie Kibler (b) (4)	31 Aug 2020 21:27:18
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Jun 2021 15:16:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	31 Aug 2020 21:27:18
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:16:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'un UNK 2020' reason for change: Data Entry Error	Trent Davis (b) (4)	15 Dec 2020 16:20:07
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	31 Aug 2020 21:27:18
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 11 Jun 2021 15:16:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Trent Davis (b) (4)	15 Dec 2020 16:20:07
	(b) (4)	
User entered '1'	Carrie Kibler (b) (4)	31 Aug 2020 21:27:18
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	31 Aug 2020 21:27:18
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Jun 2021 15:16:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	31 Aug 2020 21:27:18
	(b) (4)	

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	31 Aug 2020 21:27:18
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 21:27:18

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 21:27:18

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Aug 2020 21:27:18

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: OTHER TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, PRODUCT: CAMPHOR;EUCALYPTUS SPP. OIL;MENTHOL, PRODUCTSYNONYM: VAPORUB - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Nov 2020 16:25:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	01 Nov 2020 16:25:05
Data point term sent to Coder	System	28 Oct 2020 20:08:59
User entered 'vick's vaporub'	Carrie Kibler (b) (4)	28 Oct 2020 20:08:03
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:16:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:08:03
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'forehead pain'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 20:08:03

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'I'	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:08:03

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:16:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Other (OTHER)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 20:08:03

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:16:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'teaspoon'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 20:08:03

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:16:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'once (ONCE)'	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:08:03

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:16:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:08:03

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Topical (TOPICAL)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 20:08:03

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:16:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:08:03
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '19 Oct 2020'	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:08:03
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '0'	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:08:03

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:08:03

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:16:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '19 Oct 2020'	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:08:03
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 11 Jun 2021 15:16:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:08:03

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:53
User entered empty.	System	28 Oct 2020 20:08:03

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:53
User entered empty.	System	28 Oct 2020 20:08:03

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:53
User entered empty.	System	28 Oct 2020 20:08:03

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 20:02:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Oct 2020 20:02:31
Data point term sent to Coder	System	28 Oct 2020 20:10:03
User entered 'flu vaccine'	Carrie Kibler (b) (4)	28 Oct 2020 20:09:10

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 20:09:10

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'influenza'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 20:09:10

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '0.5'	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:09:10

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:16:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'mL (mL)'	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:09:10

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:16:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:09:10

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:16:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'once (ONCE)'	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:09:10

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:16:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:09:10

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:16:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:09:10

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:16:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:09:10

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:16:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '21 Oct 2020'	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:09:10

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '0'	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:09:10

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:09:10

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:16:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '21 Oct 2020'	(b) (4) Carrie Kibler (b) (4)	28 Oct 2020 20:09:10
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 11 Jun 2021 15:16:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	28 Oct 2020 20:09:10

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:57
User entered empty.	System	28 Oct 2020 20:09:10

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:57
User entered empty.	System	28 Oct 2020 20:09:10

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:58:57
User entered empty.	System	28 Oct 2020 20:09:10

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:16:15

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 13:49:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 13:49:45
Data point term sent to Coder Coding entries removed.	System Carrie Kibler (b) (4)	19 Feb 2021 17:25:21 19 Feb 2021 17:25:13
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Feb 2021 17:23:55
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 17:23:55
Data point term sent to Coder Coding entries removed.	System Carrie Kibler (b) (4)	19 Feb 2021 17:23:18 19 Feb 2021 17:22:43

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STERIODS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 16:44:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 16:44:49
Data point term sent to Coder	System	16 Dec 2020 19:17:48
User entered 'Advil'	Trent Davis (b) (4) (b) (4)	16 Dec 2020 19:17:15

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:16:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	16 Dec 2020 19:17:15

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User closed query 'Per DM CLR: Please note that this condition is not present in either AE and eDiary. Review indication and ensure that there is a corresponding condition recorded in the most applicable eCRF. Update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 10:11:27
User entered 'general pain post vaccination reactogenicity symptoms' reason for change: Data Entry Error	Carrie Kibler (b) (4)	19 Feb 2021 17:25:13
Query 'Per DM CLR: Please note that this condition is not present in either AE and eDiary. Review indication and ensure that there is a corresponding condition recorded in the most applicable eCRF. Update as appropriate. Otherwise, provide clarification.	Carrie Kibler (b) (4)	19 Feb 2021 17:23:44
' answered with 'post 2nd dose headache. refer to ediary' (Site from DM).		
User entered 'HEADache' reason for change: Data Entry Error	Carrie Kibler (b) (4)	19 Feb 2021 17:22:43
User opened query 'Per DM CLR: Please note that this condition is not present in either AE and eDiary. Review indication and ensure that there is a corresponding condition recorded in the most applicable eCRF. Update as appropriate. Otherwise, provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 07:08:05
User entered 'Head PAin'	Trent Davis (b) (4)	16 Dec 2020 19:17:15

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:16:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '200'	(b) (4) Trent Davis (b) (4)	16 Dec 2020 19:17:15

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:16:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'mg (mg)'	(b) (4) Trent Davis (b) (4)	16 Dec 2020 19:17:15

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:16:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Trent Davis (b) (4)	16 Dec 2020 19:17:15
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:16:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'as needed (PRN)'	(b) (4) Trent Davis (b) (4)	16 Dec 2020 19:17:15

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:16:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Trent Davis (b) (4)	16 Dec 2020 19:17:15
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	16 Dec 2020 19:17:15

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:16:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Trent Davis (b) (4)	16 Dec 2020 19:17:15
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:16:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '04 Oct 2020'	(b) (4) Trent Davis (b) (4)	16 Dec 2020 19:17:15
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '0'	(b) (4) Trent Davis (b) (4)	16 Dec 2020 19:17:15

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	16 Dec 2020 19:17:15

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Jun 2021 15:16:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '04 Oct 2020'	(b) (4) Trent Davis (b) (4)	16 Dec 2020 19:17:15
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 11 Jun 2021 15:16:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:00
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of GENERAL PAIN POST VACCINATION REACTOGENICITY SYMPTOMS in eDiary. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification '(Site from DM).		16 Apr 2021 09:25:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of GENERAL PAIN POST VACCINATION REACTOGENICITY SYMPTOMS in eDiary. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification 'answered with 'AE#2' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:14:44
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, there is no record of GENERAL PAIN POST VACCINATION REACTOGENICITY SYMPTOMS in eDiary. Review if this is considered as unsolicited event per protocol. If yes, please update and record this condition in AE eCRF and update this field to No. Else, provide clarification '(Site from DM).	(b) (4), (b) (6)	06 Mar 2021 14:27:19
User entered 'Yes (Y)'	Trent Davis (b) (4) (b) (4)	16 Dec 2020 19:17:15

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:00
User entered empty.	System	16 Dec 2020 19:17:15

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:00
User entered empty.	System	16 Dec 2020 19:17:15

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:00
User entered empty.	System	16 Dec 2020 19:17:15

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Feb 2021 19:55:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Feb 2021 19:55:46
Data point term sent to Coder	System	19 Feb 2021 17:30:26
User entered 'ibuprofen'	Carrie Kibler (b) (4)	19 Feb 2021 17:29:31

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Jun 2021 15:16:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	19 Feb 2021 17:29:31

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'prophylaxis post vaccine reactogenicity symptoms'	(b) (4) Carrie Kibler (b) (4)	19 Feb 2021 17:29:31

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:16:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '400'	(b) (4) Carrie Kibler (b) (4)	19 Feb 2021 17:29:31

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:16:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'mg (mg)'	(b) (4) Carrie Kibler (b) (4)	19 Feb 2021 17:29:31

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:16:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Carrie Kibler (b) (4)	19 Feb 2021 17:29:31

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:16:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'once (ONCE)'	(b) (4) Carrie Kibler (b) (4)	19 Feb 2021 17:29:31
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:16:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Carrie Kibler (b) (4)	19 Feb 2021 17:29:31
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Jun 2021 15:16:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Oral (ORAL)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	19 Feb 2021 17:29:31

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:16:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Carrie Kibler (b) (4)	19 Feb 2021 17:29:31

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:16:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '12 Feb 2021'	(b) (4) Carrie Kibler (b) (4)	19 Feb 2021 17:29:31
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '0'	(b) (4) Carrie Kibler (b) (4)	19 Feb 2021 17:29:31

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	19 Feb 2021 17:29:31
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:16:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '12 Feb 2021'	(b) (4) Carrie Kibler (b) (4)	19 Feb 2021 17:29:31
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 11 Jun 2021 15:16:15

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:05
User closed query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, indication records prophylactic use - 'PROPHYLAXIS POST VACCINE REACTOGENICITY SYMPTOMS'. Review if this field should be updated to No as there is no record of this event in the diary. Else, clarify ' (Site from DM).		16 Apr 2021 13:08:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
Query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, indication records prophylactic use - 'PROPHYLAXIS POST VACCINE REACTOGENICITY SYMPTOMS'. Review if this field should be updated to No as there is no record of this event in the diary. Else, clarify ' answered with 'data correction done ' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:19:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 16:18:24
User opened query 'Per DM CLR: Was this medication taken for solicited event?=YES. However, indication records prophylactic use - 'PROPHYLAXIS POST VACCINE REACTOGENICITY SYMPTOMS'. Review if this field should be updated to No as there is no record of this event in the diary. Else, clarify ' (Site from DM).		06 Mar 2021 14:28:50
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	19 Feb 2021 17:29:31

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Jun 2021 15:16:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:05
User entered empty.	System	19 Feb 2021 17:29:31

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:05
User entered empty.	System	19 Feb 2021 17:29:31

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:05
User entered empty.	System	19 Feb 2021 17:29:31

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: SECOND-GENERATION CEPHALOSPORINS, PRODUCT: CEFUROXIME AXETIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 09:08:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Mar 2021 09:08:34
Data point term sent to Coder	System	22 Mar 2021 23:54:51
Coding entries removed.	Thea Marie Cordero	22 Mar 2021 23:54:33
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:59:58
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: SECOND-GENERATION CEPHALOSPORINS, PRODUCT: CEFUROXIME AXETIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 21:11:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 21:11:51
Data point term sent to Coder	System	17 Mar 2021 18:54:48
User entered 'CEFUROXIME AXETIL'	Thea Marie Cordero	17 Mar 2021 18:54:01

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Jun 2021 15:16:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:00:01
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:54:01

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:16:15

Indication

Audit	User	Time (GMT)
User entered 'PROPHYLAXIS FOR INFECTION POST LAPAROSCOPIC SURGERY DUE TO NEPHROLITHIASIS' (WR#5445128)	System	11 Jun 2021 14:45:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:10
DataPoint Verified.		16 Apr 2021 17:42:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Un-verified.	(b) (4)	
	Thea Marie Cordero	22 Mar 2021 23:54:33
	(b) (4)	
User entered 'PROPHYLAXIS FOR INFECTION POST LAPAROSCOPIC SURGERY DUE TO NEPHROLITHIASIS' reason for change:	Thea Marie Cordero	22 Mar 2021 23:54:33
New Information	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:00:03
User entered 'PROPHYLAXIS FOR INFECTION POST LAPAROSCOPIC SURGERY'	Thea Marie Cordero	17 Mar 2021 18:54:01
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Jun 2021 15:16:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:00:05
User entered '250'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:54:01

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Jun 2021 15:16:15**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:00:08
User entered 'mg (mg)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:54:01

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:16:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:00:09
User entered empty.	Thea Marie Cordero (b) (4)	17 Mar 2021 18:54:01

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Jun 2021 15:16:15**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:00:11
User entered 'twice daily (BID)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:54:01

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:16:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:00:13
User entered empty.	Thea Marie Cordero (b) (4)	17 Mar 2021 18:54:01

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Jun 2021 15:16:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:00:14
User entered 'Oral (ORAL)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:54:01

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:16:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:00:17
User entered empty.	Thea Marie Cordero (b) (4)	17 Mar 2021 18:54:01

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:00:18
User entered '15 Mar 2021'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:54:01

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:00:20
User entered '0'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:54:01

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:16:15

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:10
DataPoint Verified.		16 Apr 2021 16:58:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Un-verified.	(b) (4) Thea Marie Cordero	22 Mar 2021 23:53:29
User entered 'No (N)' reason for change: New Information	(b) (4) Thea Marie Cordero	22 Mar 2021 23:53:29
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:00:22
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:54:01

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 11 Jun 2021 15:16:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:10
DataPoint Verified.		16 Apr 2021 16:58:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Un-verified.	(b) (4)	22 Mar 2021 23:53:29
User entered '21 Mar 2021' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	22 Mar 2021 23:53:29
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:00:23
User entered empty.	Thea Marie Cordero (b) (4)	17 Mar 2021 18:54:01

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 18:00:26
User entered 'No (N)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:54:01

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Jun 2021 15:16:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:10
User entered '2'	System	17 Mar 2021 18:54:01

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:10
User entered '1'	System	17 Mar 2021 18:54:01

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:10
User entered '804 (804)'	System	17 Mar 2021 18:54:01

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:16:15

Name of Medication

Audit	User	Time (GMT)
User entered 'HYDROCODONE/ ACETAMINOPHEN' (WR#5445128)	System	11 Jun 2021 14:45:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 14:29:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:29:49
Data point term sent to Coder	System	19 Mar 2021 16:17:48
Coding entries removed.	(b) (4), (b) (6)	19 Mar 2021 16:17:42
DataPoint Verified.	(b) (4)	18 Mar 2021 18:00:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:47:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 21:47:55
Data point term sent to Coder	System	17 Mar 2021 18:56:50
User entered 'HYDROCODONE/ ACETAMINOPHEN'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:56:23

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Jun 2021 15:16:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:00:44
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:56:23

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Please update indication to include that this was due to nephrolithiasis in order to link the medication to the SAE.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 16:58:37
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 16:58:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
Query 'Please update indication to include that this was due to nephrolithiasis in order to link the medication to the SAE.' answered with 'data updated ' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 16:17:52
User entered 'PROPHYLAXIS FOR PAIN POST LAPAROSCOPIC SURGERY(due to nephrolithiasis)' reason for change: Per Query Resolution	(b) (4), (b) (6)	19 Mar 2021 16:17:42
User opened query 'Please update indication to include that this was due to nephrolithiasis in order to link the medication to the SAE.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 18:04:20
User entered 'PROPHYLAXIS FOR PAIN POST LAPAROSCOPIC SURGERY'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:56:23

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Jun 2021 15:16:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:00:47
User entered '5/325'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:56:23

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:16:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:00:50
User entered 'mg (mg)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:56:23

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:16:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 18:00:53
User entered empty.	Thea Marie Cordero	17 Mar 2021 18:56:23
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:16:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 18:00:54
User entered 'other (OTHER)'	Thea Marie Cordero	17 Mar 2021 18:56:23
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:16:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:00:56
User entered 'EVERY 4 HOURS AS NEEDED'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:56:23

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Jun 2021 15:16:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 18:00:59
User entered 'Oral (ORAL)'	Thea Marie Cordero	17 Mar 2021 18:56:23
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:16:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 18:01:02
User entered empty.	Thea Marie Cordero	17 Mar 2021 18:56:23
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:16:15

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 18:01:03
User entered '15 Mar 2021'	Thea Marie Cordero	17 Mar 2021 18:56:23
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:16:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 18:01:05
User entered '0'	Thea Marie Cordero	17 Mar 2021 18:56:23
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:01:07
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:56:23

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:16:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 18:01:08
User entered empty.	Thea Marie Cordero	17 Mar 2021 18:56:23
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 11 Jun 2021 15:16:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:01:11
User entered 'No (N)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:56:23

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Jun 2021 15:16:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 18:56:23

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 18:56:23

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 18:56:23

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:16:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: AZO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Mar 2021 03:33:36
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Mar 2021 03:33:36
	(b) (4)	
Data point term sent to Coder	System	19 Mar 2021 16:20:49
Coding entries removed.	(b) (4), (b) (6)	19 Mar 2021 16:19:55
DataPoint Verified.		18 Mar 2021 18:02:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN, PRODUCTSYNONYM: AZO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 21:09:57
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Mar 2021 21:09:57
	(b) (4)	
Data point term sent to Coder	System	17 Mar 2021 18:57:50
User entered 'AZO TABLET'	Thea Marie Cordero	17 Mar 2021 18:57:35
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Jun 2021 15:16:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:02:55
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:57:35

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:42:20
User closed query 'Please update indication to include that this was due to nephrolithiasis in order to link the medication to the SAE.' (Site from CRA).		16 Apr 2021 17:42:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
Query 'Please update indication to include that this was due to nephrolithiasis in order to link the medication to the SAE.' answered with 'data correction done ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Mar 2021 16:20:03
User entered 'PROPHYLAXIS FOR PAIN POST LAPAROSCOPIC SURGERY (due to nephrolithiasis)' reason for change: Per Query Resolution	(b) (4), (b) (6)	19 Mar 2021 16:19:55
User opened query 'Please update indication to include that this was due to nephrolithiasis in order to link the medication to the SAE.' (Site from CRA).	(b) (4), (b) (6)	18 Mar 2021 18:04:10
User entered 'PROPHYLAXIS FOR PAIN POST LAPAROSCOPIC SURGERY'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:57:35

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:16:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:03:04
User entered '95'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:57:35

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:16:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:03:06
User entered 'mg (mg)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:57:35

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:16:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:03:08
User entered empty.	Thea Marie Cordero (b) (4)	17 Mar 2021 18:57:35

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Jun 2021 15:16:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:03:10
User entered 'other (OTHER)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:57:35

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:16:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 18:03:12
User entered 'TID AS NEEDED'	Thea Marie Cordero	17 Mar 2021 18:57:35
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:16:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:03:13
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 18:57:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Mar 2021 18:57:49
User entered 'Oral (ORAL)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	17 Mar 2021 18:57:49
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Mar 2021 18:57:35
User entered empty.	Thea Marie Cordero (b) (4)	17 Mar 2021 18:57:35

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:16:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 18:03:15
User entered empty.	Thea Marie Cordero	17 Mar 2021 18:57:35
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:16:15

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 18:03:19
User entered '15 Mar 2021'	Thea Marie Cordero	17 Mar 2021 18:57:35
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:16:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:03:23
User entered '0'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:57:35

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:03:25
User entered 'Yes (Y)'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:57:35

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 11 Jun 2021 15:16:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:03:27
User entered empty.	Thea Marie Cordero (b) (4)	17 Mar 2021 18:57:35

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 18:03:30
User entered 'No (N)'	Thea Marie Cordero	17 Mar 2021 18:57:35
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Jun 2021 15:16:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 18:57:35

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 18:57:35

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Mar 2021 18:57:35

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS FOR URINARY FREQUENCY AND INCONTINENCE, PRODUCT: TOLTERODINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 09:00:31
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 09:00:31
Data point term sent to Coder	System	23 Mar 2021 00:01:00
User entered 'TOLTERODINE'	Thea Marie Cordero (b) (4)	23 Mar 2021 00:00:11

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Jun 2021 15:16:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	23 Mar 2021 00:00:11
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Jun 2021 15:16:15**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'PROPHYLAXIS FOR URINARY SPASM'	(b) (4) Thea Marie Cordero	23 Mar 2021 00:00:11

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:16:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '4'	(b) (4) Thea Marie Cordero	23 Mar 2021 00:00:11
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:16:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'mg (mg)'	(b) (4) Thea Marie Cordero	23 Mar 2021 00:00:11
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:16:15

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Thea Marie Cordero	23 Mar 2021 00:00:11
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:16:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'once daily (QD)'	(b) (4) Thea Marie Cordero	23 Mar 2021 00:00:11
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:16:15

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Thea Marie Cordero	23 Mar 2021 00:00:11
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:16:15

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Oral (ORAL)'	(b) (4) Thea Marie Cordero	23 Mar 2021 00:00:11
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:16:15

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Thea Marie Cordero	23 Mar 2021 00:00:11
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:16:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '22 Mar 2021'	(b) (4) Thea Marie Cordero	23 Mar 2021 00:00:11
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:16:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '0'	(b) (4) Thea Marie Cordero	23 Mar 2021 00:00:11
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	23 Mar 2021 00:00:11
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Jun 2021 15:16:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Thea Marie Cordero	23 Mar 2021 00:00:11
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 11 Jun 2021 15:16:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:50:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'No (N)'	(b) (4) Thea Marie Cordero	23 Mar 2021 00:00:11
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Jun 2021 15:16:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 00:00:11

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 00:00:11

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Mar 2021 00:00:11

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:19
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 DIHYDRATE;POTASSIUM CHLORIDE;SODIUM CHLORIDE;SODIUM LACTATE, PRODUCTSYNONYM: LACTATED RINGER'S - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:24:39
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 07:24:39
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:20:39
Data point term sent to Coder	System	27 Mar 2021 01:17:13
User entered 'LACTATED RINGER'S INFUSION'	Thea Marie Cordero (b) (4)	27 Mar 2021 01:00:25

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Jun 2021 15:16:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'No (N)'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:00:25
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
User entered 'LEFT PROXIMAL AND DISTAL URETERAL CALCULI NON OBSTRUCTING LEFT NEPHROLITHIASIS' (WR#5445128)	System	11 Jun 2021 14:45:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'LEFT PROXIMAL AND DISTAL URETERAL CALCULI	(b) (4) Thea Marie Cordero	27 Mar 2021 01:00:25
	(b) (4)	

NON OBSTRUCTING LEFT NEPHROLITHIASIS'

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Jun 2021 15:16:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '50'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:00:25
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:16:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Other (OTHER)'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:00:25
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:16:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'ML/HR' reason for change: Data Entry Error	(b) (4)	27 Mar 2021 01:11:50
User entered '50 ML/HR'	Thea Marie Cordero	27 Mar 2021 01:00:25
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:16:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'other (OTHER)'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:00:25
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:16:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'CONTINUOUS INFUSION'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:00:25
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:16:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:00:25

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:16:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Thea Marie Cordero	27 Mar 2021 01:00:25
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '13 Mar 2021'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:00:25
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '0'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:00:25
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'No (N)'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:00:25
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Jun 2021 15:16:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '14 Mar 2021'	(b) (4)	27 Mar 2021 01:00:25

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 11 Jun 2021 15:16:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'No (N)'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:00:25
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Jun 2021 15:16:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:19
User entered empty.	System	27 Mar 2021 01:00:25

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:19
User entered empty.	System	27 Mar 2021 01:00:25

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:19
User entered empty.	System	27 Mar 2021 01:00:25

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:23
DataPoint Verified.		16 Apr 2021 17:27:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
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)	30 Mar 2021 09:57:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 09:57:43
Data point term sent to Coder	System	27 Mar 2021 01:17:12
User entered 'MORPHINE'	Thea Marie Cordero (b) (4)	27 Mar 2021 01:02:52

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:16:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:23
DataPoint Verified.		16 Apr 2021 17:27:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	27 Mar 2021 01:02:52
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
User entered 'LEFT PROXIMAL AND DISTAL URETERAL CALCULI NON OBSTRUCTING LEFT NEPHROLITHIASIS' (WR#5445128)	System	11 Jun 2021 14:45:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:23
DataPoint Verified.		16 Apr 2021 17:27:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'LEFT PROXIMAL AND DISTAL URETERAL CALCULI	Thea Marie Cordero	27 Mar 2021 01:02:52
	(b) (4)	

NON OBSTRUCTING LEFT NEPHROLITHIASIS'

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Jun 2021 15:16:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:23
DataPoint Verified.		16 Apr 2021 17:27:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '4'	Thea Marie Cordero	27 Mar 2021 01:02:52
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:16:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:23
DataPoint Verified.		16 Apr 2021 17:27:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'mg (mg)'	Thea Marie Cordero	27 Mar 2021 01:02:52
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:16:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:23
DataPoint Verified.		16 Apr 2021 17:27:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Thea Marie Cordero (b) (4)	27 Mar 2021 01:02:52

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:16:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:23
DataPoint Verified.		16 Apr 2021 17:27:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'other (OTHER)'	Thea Marie Cordero	27 Mar 2021 01:02:52
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:16:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:23
DataPoint Verified.		16 Apr 2021 17:27:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'EVERY 4 HOURS AS NEEDED'	Thea Marie Cordero	27 Mar 2021 01:02:52
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:16:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:23
DataPoint Verified.		16 Apr 2021 17:27:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	Thea Marie Cordero	27 Mar 2021 01:02:52
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:16:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:23
DataPoint Verified.		16 Apr 2021 17:27:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4)	27 Mar 2021 01:02:52
	Thea Marie Cordero	
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 11 Jun 2021 15:16:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:23
DataPoint Verified.		16 Apr 2021 17:27:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '13 Mar 2021'	Thea Marie Cordero	27 Mar 2021 01:02:52
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:23
DataPoint Verified.		16 Apr 2021 17:27:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '0'	Thea Marie Cordero	27 Mar 2021 01:02:52
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:23
DataPoint Verified.		16 Apr 2021 17:27:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'No (N)'	(b) (4) Thea Marie Cordero (b) (4)	27 Mar 2021 01:02:52

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Jun 2021 15:16:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:23
DataPoint Verified.		16 Apr 2021 17:27:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '14 Mar 2021'	Thea Marie Cordero	27 Mar 2021 01:02:52
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:23
DataPoint Verified.		16 Apr 2021 17:27:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	27 Mar 2021 01:02:52
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Jun 2021 15:16:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:23
User entered empty.	System	27 Mar 2021 01:02:52

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:23
User entered empty.	System	27 Mar 2021 01:02:52

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:23
User entered empty.	System	27 Mar 2021 01:02:52

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
DataPoint Verified.		16 Apr 2021 17:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: OTHER UROLOGICALS, PRODUCT: PHENAZOPYRIDINE HYDROCHLORIDE, PRODUCTSYNONYM: PYRIDIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Mar 2021 01:19:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Mar 2021 01:19:00
Data point term sent to Coder	System	27 Mar 2021 01:17:14
User entered 'PYRIDIUM'	Thea Marie Cordero (b) (4)	27 Mar 2021 01:04:05

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:16:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
DataPoint Verified.		16 Apr 2021 17:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	27 Mar 2021 01:04:05
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
User entered 'LEFT PROXIMAL AND DISTAL URETERAL CALCULI NON OBSTRUCTING LEFT NEPHROLITHIASIS' (WR#5445128)	System	11 Jun 2021 14:45:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
DataPoint Verified.		16 Apr 2021 17:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'LEFT PROXIMAL AND DISTAL URETERAL CALCULI	Thea Marie Cordero	27 Mar 2021 01:04:05
	(b) (4)	

NON OBSTRUCTING LEFT NEPHROLITHIASIS'

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Jun 2021 15:16:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
DataPoint Verified.		16 Apr 2021 17:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '100'	(b) (4)	27 Mar 2021 01:04:05
	Thea Marie Cordero	
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:16:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
DataPoint Verified.		16 Apr 2021 17:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'mg (mg)'	Thea Marie Cordero	27 Mar 2021 01:04:05
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:16:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
DataPoint Verified.		16 Apr 2021 17:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4)	27 Mar 2021 01:04:05
	Thea Marie Cordero	
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:16:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
DataPoint Verified.		16 Apr 2021 17:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'three times daily (TID)'	Thea Marie Cordero	27 Mar 2021 01:04:05
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:16:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
DataPoint Verified.		16 Apr 2021 17:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4)	27 Mar 2021 01:04:05
	Thea Marie Cordero	
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Jun 2021 15:16:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
DataPoint Verified.		16 Apr 2021 17:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Oral (ORAL)'	Thea Marie Cordero	27 Mar 2021 01:04:05
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:16:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
DataPoint Verified.		16 Apr 2021 17:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Thea Marie Cordero	27 Mar 2021 01:04:05
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:16:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
DataPoint Verified.		16 Apr 2021 17:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '13 Mar 2021'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:04:05
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
DataPoint Verified.		16 Apr 2021 17:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '0'	Thea Marie Cordero	27 Mar 2021 01:04:05
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
DataPoint Verified.		16 Apr 2021 17:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'No (N)'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:04:05
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Jun 2021 15:16:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
DataPoint Verified.		16 Apr 2021 17:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '14 Mar 2021'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:04:05
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 11 Jun 2021 15:16:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
DataPoint Verified.		16 Apr 2021 17:15:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	27 Mar 2021 01:04:05
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Jun 2021 15:16:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
User entered '3'	System	27 Mar 2021 01:04:05

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
User entered '1'	System	27 Mar 2021 01:04:05

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:27
User entered '804 (804)'	System	27 Mar 2021 01:04:05

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
DataPoint Verified.		16 Apr 2021 17:17:37
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: OSMOTICALLY ACTING LAXATIVES, PRODUCT: MACROGOL 3350, PRODUCTSYNONYM: MIRALAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Mar 2021 01:19:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Mar 2021 01:19:00
Data point term sent to Coder	System	27 Mar 2021 01:17:13
User entered 'MIRALAX'	Thea Marie Cordero (b) (4)	27 Mar 2021 01:06:20

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 11 Jun 2021 15:16:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
DataPoint Verified.		16 Apr 2021 17:17:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	27 Mar 2021 01:06:20
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
User entered 'LEFT PROXIMAL AND DISTAL URETERAL CALCULI NON OBSTRUCTING LEFT NEPHROLITHIASIS' (WR#5445128)	System	11 Jun 2021 14:45:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
DataPoint Verified.		16 Apr 2021 17:17:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'LEFT PROXIMAL AND DISTAL URETERAL CALCULI	Thea Marie Cordero	27 Mar 2021 01:06:20
	(b) (4)	

NON OBSTRUCTING LEFT NEPHROLITHIASIS'

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:16:15

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
DataPoint Verified.		16 Apr 2021 17:17:34
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '17'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:06:20
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 11 Jun 2021 15:16:15**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
DataPoint Verified.		16 Apr 2021 17:17:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'g (g)'	Thea Marie Cordero	27 Mar 2021 01:06:20
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:16:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
DataPoint Verified.		16 Apr 2021 17:17:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4)	27 Mar 2021 01:06:20
	Thea Marie Cordero	
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:16:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
DataPoint Verified.		16 Apr 2021 17:17:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'twice daily (BID)'	Thea Marie Cordero	27 Mar 2021 01:06:20
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:16:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
DataPoint Verified.		16 Apr 2021 17:17:23
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4)	27 Mar 2021 01:06:20
	Thea Marie Cordero	
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 11 Jun 2021 15:16:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
DataPoint Verified.		16 Apr 2021 17:17:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Oral (ORAL)'	Thea Marie Cordero	27 Mar 2021 01:06:20
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:16:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
DataPoint Verified.		16 Apr 2021 17:17:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4)	27 Mar 2021 01:06:20
	Thea Marie Cordero	
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:16:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
DataPoint Verified.		23 Apr 2021 14:44:41
User closed query 'As per Source ConMed, The start date is 14MAR2021. Please verify and update as needed.' (Site from CRA).		23 Apr 2021 14:44:39
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
Query 'As per Source ConMed, The start date is 14MAR2021. Please verify and update as needed.' answered with 'Updated in the EDC, Source Document Correct' (Site from CRA).	(b) (4) (b) (4), (b) (6)	20 Apr 2021 21:07:00
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 20:59:39
User entered '14 Mar 2021' reason for change: Data Entry Error		20 Apr 2021 20:59:39
User opened query 'As per Source ConMed, The start date is 14MAR2021. Please verify and update as needed.' (Site from CRA).		16 Apr 2021 17:16:54
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:20:39
User entered '13 Mar 2021'	Thea Marie Cordero (b) (4)	27 Mar 2021 01:06:20

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
DataPoint Verified.		16 Apr 2021 17:17:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '0'	Thea Marie Cordero	27 Mar 2021 01:06:20
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
DataPoint Verified.		16 Apr 2021 17:17:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'No (N)'	(b) (4) Thea Marie Cordero (b) (4)	27 Mar 2021 01:06:20

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 11 Jun 2021 15:16:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
DataPoint Verified.		16 Apr 2021 17:17:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '14 Mar 2021'	(b) (4) Thea Marie Cordero (b) (4)	27 Mar 2021 01:06:20

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:16:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
DataPoint Verified.		16 Apr 2021 17:17:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	27 Mar 2021 01:06:20
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 11 Jun 2021 15:16:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
User entered '2'	System	27 Mar 2021 01:06:20

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 11 Jun 2021 15:16:15

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
User entered '1'	System	27 Mar 2021 01:06:20

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:31
User entered '804 (804)'	System	27 Mar 2021 01:06:20

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
User closed query 'Please update Name of Medication to match the source for consistency.' (Site from CRA).		23 Apr 2021 14:45:20
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: DOCUSATE SODIUM;SENNOSIDE A+B - version WHODrug-Global-B3\\202003.	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 09:30:09
Data point term sent to Coder	(b) (4)	
Query 'Please update Name of Medication to match the source for consistency.' answered with 'UPDATED IN EDC, CORRECT PER SOURCE DOCUMENT' (Site from CRA).	System	21 Apr 2021 09:30:09
Coding entries removed.	(b) (4), (b) (6)	20 Apr 2021 22:50:51
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 22:50:36
User entered 'SENNOSIDE DOCUSATE SODIUM' reason for change: Data Entry Error		
DataPoint Un-verified.		20 Apr 2021 22:50:01
DataPoint Verified.		20 Apr 2021 22:50:01
User opened query 'Please update Name of Medication to match the source for consistency.' (Site from CRA).		16 Apr 2021 17:20:53
User signature succeeded.	Hana El Sahly (b) (4)	16 Apr 2021 17:20:47
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENOKOT - version WHODrug-Global-B3\\202003.	(b) (4)	16 Apr 2021 17:20:21
	Coder Import (b) (4)	
	(b) (4)	02 Apr 2021 14:20:39
		27 Mar 2021 01:19:01

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2381 of 2625

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	27 Mar 2021 01:19:01
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	27 Mar 2021 01:17:14
User entered 'SENOKOT'	Thea Marie Cordero	27 Mar 2021 01:08:01
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:16:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
DataPoint Verified.		16 Apr 2021 17:20:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	27 Mar 2021 01:08:09
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	27 Mar 2021 01:08:09
User entered 'No (N)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	27 Mar 2021 01:08:09
User opened query 'Data is required. Please complete.' (Site from System).	System	27 Mar 2021 01:08:01
User entered empty.	Thea Marie Cordero (b) (4)	27 Mar 2021 01:08:01

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
User entered 'LEFT PROXIMAL AND DISTAL URETERAL CALCULI NON OBSTRUCTING LEFT NEPHROLITHIASIS' (WR#5445128)	System	11 Jun 2021 14:45:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
DataPoint Verified.		16 Apr 2021 17:20:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'LEFT PROXIMAL AND DISTAL URETERAL CALCULI	Thea Marie Cordero	27 Mar 2021 01:08:01
	(b) (4)	

NON OBSTRUCTING LEFT NEPHROLITHIASIS'

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Jun 2021 15:16:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
DataPoint Verified.		16 Apr 2021 17:20:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '50'	(b) (4) Thea Marie Cordero (b) (4)	27 Mar 2021 01:08:01

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:16:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
DataPoint Verified.		16 Apr 2021 17:20:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'mg (mg)'	(b) (4) Thea Marie Cordero (b) (4)	27 Mar 2021 01:08:01

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:16:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
DataPoint Verified.		16 Apr 2021 17:20:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4)	27 Mar 2021 01:08:01
	Thea Marie Cordero	
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:16:15

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
DataPoint Verified.		16 Apr 2021 17:20:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'twice daily (BID)'	Thea Marie Cordero	27 Mar 2021 01:08:01
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:16:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
DataPoint Verified.		16 Apr 2021 17:20:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Thea Marie Cordero	27 Mar 2021 01:08:01
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Jun 2021 15:16:15**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
DataPoint Verified.		16 Apr 2021 17:20:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Oral (ORAL)'	Thea Marie Cordero	27 Mar 2021 01:08:01
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Jun 2021 15:16:15**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
DataPoint Verified.		16 Apr 2021 17:20:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4)	27 Mar 2021 01:08:01
	Thea Marie Cordero	
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
DataPoint Verified.		16 Apr 2021 17:20:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '13 Mar 2021'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:08:01
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
DataPoint Verified.		16 Apr 2021 17:20:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '0'	Thea Marie Cordero	27 Mar 2021 01:08:01
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
DataPoint Verified.		16 Apr 2021 17:20:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'No (N)'	(b) (4) Thea Marie Cordero (b) (4)	27 Mar 2021 01:08:01

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Jun 2021 15:16:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
DataPoint Verified.		16 Apr 2021 17:20:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '14 Mar 2021'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:08:01
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 11 Jun 2021 15:16:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
DataPoint Verified.		16 Apr 2021 17:20:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	27 Mar 2021 01:08:01
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Jun 2021 15:16:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
User entered '2'	System	27 Mar 2021 01:08:01

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
User entered '1'	System	27 Mar 2021 01:08:01

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:36
User entered '804 (804)'	System	27 Mar 2021 01:08:01

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:40
DataPoint Verified.	(b) (4)	16 Apr 2021 17:22:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
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: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Apr 2021 10:04:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 10:04:23
Data point term sent to Coder	System	27 Mar 2021 01:17:15
User entered 'SODIUM CHLORIDE 0.9 % INFUSION'	Thea Marie Cordero (b) (4)	27 Mar 2021 01:09:58

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:16:15

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:40
DataPoint Verified.		16 Apr 2021 17:22:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	27 Mar 2021 01:09:58
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
User entered 'LEFT PROXIMAL AND DISTAL URETERAL CALCULI NON OBSTRUCTING LEFT NEPHROLITHIASIS' (WR#5445128)	System	11 Jun 2021 14:45:08
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:40
DataPoint Verified.		16 Apr 2021 17:22:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'LEFT PROXIMAL AND DISTAL URETERAL CALCULI	Thea Marie Cordero	27 Mar 2021 01:09:58
	(b) (4)	

NON OBSTRUCTING LEFT NEPHROLITHIASIS'

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 11 Jun 2021 15:16:15**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:40
DataPoint Verified.		16 Apr 2021 17:22:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '125'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:09:58
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:16:15

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:40
DataPoint Verified.		16 Apr 2021 17:22:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Other (OTHER)' reason for change:	Thea Marie Cordero	27 Mar 2021 01:11:15
Data Entry Error	(b) (4)	
User entered 'mL (mL)'	Thea Marie Cordero	27 Mar 2021 01:09:58
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:16:15

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:40
DataPoint Verified.		16 Apr 2021 17:22:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'ML/HR' reason for change: Data Entry Error	Thea Marie Cordero	27 Mar 2021 01:11:15
	(b) (4)	
User entered empty.	Thea Marie Cordero	27 Mar 2021 01:09:58
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 11 Jun 2021 15:16:15**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:40
DataPoint Verified.		16 Apr 2021 17:22:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'other (OTHER)'	Thea Marie Cordero	27 Mar 2021 01:09:58
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:16:15

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:40
DataPoint Verified.		16 Apr 2021 17:22:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'CONTINUOUS INFUSION' reason	Thea Marie Cordero	27 Mar 2021 01:11:15
for change: Data Entry Error	(b) (4)	
User entered '125/ML'	Thea Marie Cordero	27 Mar 2021 01:09:58
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:16:15

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:40
DataPoint Verified.		16 Apr 2021 17:22:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	Thea Marie Cordero	27 Mar 2021 01:09:58
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:16:15

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:40
DataPoint Verified.		16 Apr 2021 17:22:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4)	27 Mar 2021 01:09:58
	Thea Marie Cordero	
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:40
DataPoint Verified.		16 Apr 2021 17:22:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '13 Mar 2021'	Thea Marie Cordero	27 Mar 2021 01:09:58
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:40
DataPoint Verified.		16 Apr 2021 17:22:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '0'	Thea Marie Cordero	27 Mar 2021 01:09:58
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:40
DataPoint Verified.		16 Apr 2021 17:22:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	27 Mar 2021 01:09:58
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:16:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:40
DataPoint Verified.		16 Apr 2021 17:22:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '14 Mar 2021'	Thea Marie Cordero	27 Mar 2021 01:09:58
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 11 Jun 2021 15:16:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:40
DataPoint Verified.		16 Apr 2021 17:22:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'No (N)'	Thea Marie Cordero	27 Mar 2021 01:09:58
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 11 Jun 2021 15:16:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:40
User entered empty.	System	27 Mar 2021 01:09:58

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:40
User entered empty.	System	27 Mar 2021 01:09:58

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 11:59:40
User entered empty.	System	27 Mar 2021 01:09:58

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 14:45:59
User closed query 'As per Source the Medication is reported as Tamsulosin which is a generic name for Flomax. For consistency of records, have same name in Source and EDC.' (Site from CRA).		23 Apr 2021 14:45:57
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Apr 2021 08:42:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 08:42:52
Data point term sent to Coder	System	20 Apr 2021 22:54:54
Query 'As per Source the Medication is reported as Tamsulosin which is a generic name for Flomax. For consistency of records, have same name in Source and EDC.' answered with 'UPDATED IN EDC AS IN SOURCE DOCUMENT' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 22:54:11
Coding entries removed.	(b) (4), (b) (6)	20 Apr 2021 22:53:54
Signature has been broken.		20 Apr 2021 22:53:54
User entered 'TAMSULOSIN' reason for change: Data Entry Error		20 Apr 2021 22:53:54
User opened query 'As per Source the Medication is reported as Tamsulosin which is a generic name for Flomax. For consistency of records, have same name in Source and EDC.' (Site from CRA).		16 Apr 2021 18:39:38
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 18:37:09
DataPoint Verified.		16 Apr 2021 17:24:13
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:20:39

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN HYDROCHLORIDE, PRODUCTSYNONYM: FLOMAX [TAMSULOSIN HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 14:03:30
Data point term sent to Coder	System	27 Mar 2021 01:17:14
User entered 'FLOMAX'	Thea Marie Cordero (b) (4)	27 Mar 2021 01:12:54

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 11 Jun 2021 15:16:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:24:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'No (N)'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:12:54
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
User entered 'LEFT PROXIMAL AND DISTAL URETERAL CALCULI NON OBSTRUCTING LEFT NEPHROLITHIASIS' (WR#5445128)	System	11 Jun 2021 14:45:08
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:24:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'LEFT PROXIMAL AND DISTAL URETERAL CALCULI	(b) (4) Thea Marie Cordero	27 Mar 2021 01:12:54
	(b) (4)	

NON OBSTRUCTING LEFT NEPHROLITHIASIS'

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:16:15

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:24:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '0.4'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:12:54
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:16:15

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:24:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'mg (mg)'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:12:54
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:16:15

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:24:23
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Thea Marie Cordero	27 Mar 2021 01:12:54
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:16:15

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:24:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'once daily (QD)'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:12:54
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:16:15

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:24:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Thea Marie Cordero	27 Mar 2021 01:12:54
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 11 Jun 2021 15:16:15**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:24:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Oral (ORAL)'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:12:54
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:16:15

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:24:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4) Thea Marie Cordero	27 Mar 2021 01:12:54
	(b) (4)	

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 11 Jun 2021 15:16:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per Medical records, start date is 22FEB2021. Please verify and update as needed' (Site from CRA).	(b) (4), (b) (6)	03 May 2021 12:53:01
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
Query 'Per Medical records, start date is 22FEB2021. Please verify and update as needed' answered with 'THERE IS NO DOCUMENTATION TO ATTEST THAT THE PARTICIPANT RECEIVED PRESCRIPTION FOR TAMSULOSIN FOR VOIDING ISSUES. ' (Site from CRA).	(b) (4), (b) (6)	0 Apr 2021 23:01:02
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 22:58:11
User entered '14 Mar 2021' reason for change: Data Entry Error		20 Apr 2021 22:58:11
User opened query 'Per Medical records, start date is 22FEB2021. Please verify and update as needed' (Site from CRA).		16 Apr 2021 17:26:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '13 Mar 2021'	Thea Marie Cordero (b) (4)	27 Mar 2021 01:12:54

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:24:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '0'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:12:54
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:24:34
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'No (N)'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:12:54
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 11 Jun 2021 15:16:15**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:24:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '14 Mar 2021'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:12:54
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:24:37
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'No (N)'	(b) (4) Thea Marie Cordero	27 Mar 2021 01:12:54
	(b) (4)	

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 11 Jun 2021 15:16:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Mar 2021 01:12:54

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Mar 2021 01:12:54

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Mar 2021 01:12:54

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: SECOND-GENERATION CEPHALOSPORINS, PRODUCT: CEFUROXIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 06:20:03
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 06:20:03
	(b) (4)	
Data point term sent to Coder	System	20 Apr 2021 23:09:02
Data point term sent to Coder	System	20 Apr 2021 23:04:59
User entered 'CEFUROXIME'	(b) (4), (b) (6)	20 Apr 2021 23:04:53

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:16:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 23:04:53

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered 'URETHRAL STENT REMOVAL'	(b) (4), (b) (6)	20 Apr 2021 23:08:12
reason for change: Data Entry Error		
User entered 'NON OBSTRUCTIVE LEFT RENAL CALCULI'	(b) (4), (b) (6)	20 Apr 2021 23:04:53

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 11 Jun 2021 15:16:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered '500' reason for change: Data Entry	(b) (4)	20 Apr 2021 23:07:15
Error	(b) (4), (b) (6)	
User entered '250'		20 Apr 2021 23:04:53

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:16:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 23:04:53

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 11 Jun 2021 15:16:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 23:04:53

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 11 Jun 2021 15:16:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 23:04:53

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:16:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 23:04:53

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 11 Jun 2021 15:16:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 23:04:53

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 11 Jun 2021 15:16:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 23:04:53

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:16:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered '19 Apr 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 23:07:15
User entered '14 Mar 2021'	(b) (4), (b) (6)	20 Apr 2021 23:04:53

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 23:04:53

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 11 Jun 2021 15:16:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Apr 2021 23:07:15
User entered 'No (N)'		20 Apr 2021 23:04:53

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 11 Jun 2021 15:16:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	20 Apr 2021 23:07:15
User entered '21 Mar 2021'		20 Apr 2021 23:04:53

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 11 Jun 2021 15:16:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 23:04:53

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 11 Jun 2021 15:16:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	20 Apr 2021 23:04:53

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Apr 2021 23:04:53

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Apr 2021 23:04:53

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:16:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: CODEINE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;CODEINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Apr 2021 06:22:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 06:22:52
Data point term sent to Coder	System	20 Apr 2021 23:13:04
User entered 'CODEINE/ACETOMINOPHEN'	(b) (4), (b) (6) (b) (4)	20 Apr 2021 23:13:00

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:16:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered 'No (N)'	(b) (4), (b) (6)	20 Apr 2021 23:13:00

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 11 Jun 2021 15:16:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered 'URETHRAL STENT REMOVAL'	(b) (4), (b) (6)	20 Apr 2021 23:13:00

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:16:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered '30/300'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 23:13:00

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:16:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 23:13:00

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 11 Jun 2021 15:16:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 23:13:00

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 11 Jun 2021 15:16:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 23:13:00

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:16:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 23:13:00

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 11 Jun 2021 15:16:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	20 Apr 2021 23:13:00

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:16:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 23:13:00

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 23:13:00

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 11 Jun 2021 15:16:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered '0'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 23:13:00

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:16:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
	(b) (4)	
Signature has been broken.	Thea Marie Cordero	26 Apr 2021 17:47:50
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Thea Marie Cordero	26 Apr 2021 17:47:50
	(b) (4)	
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 23:13:00

US3862099

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 11 Jun 2021 15:16:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
	(b) (4)	
Signature has been broken.	Thea Marie Cordero	26 Apr 2021 17:47:50
	(b) (4)	
User entered '21 Apr 2021' reason for change: New Information	Thea Marie Cordero	26 Apr 2021 17:47:50
	(b) (4)	
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 23:13:00

US3862099

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 11 Jun 2021 15:16:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 23:13:00

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 11 Jun 2021 15:16:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 23:13:00

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 23:13:00

**US3862099**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 11 Jun 2021 15:16:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Apr 2021 23:13:00

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 11 Jun 2021 15:16:15

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:04:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 18:04:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Mar 2021 18:04:27
	Thea Marie Cordero	17 Mar 2021 18:58:54
	(b) (4)	

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Jun 2021 15:16:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 18:04:42
User entered '14 Mar 2021'	(b) (4), (b) (6)	18 Mar 2021 18:04:42
	Thea Marie Cordero	17 Mar 2021 18:59:58
	(b) (4)	

**US3862099**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:04:42
User entered 'URETERAL STENT PLACEMENT'	Thea Marie Cordero (b) (4)	17 Mar 2021 18:59:58

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 18:04:42
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	17 Mar 2021 18:59:58
	Thea Marie Cordero	
	(b) (4)	

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 11 Jun 2021 15:16:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 18:04:42
User entered empty.	Thea Marie Cordero (b) (4)	17 Mar 2021 18:59:58

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Jun 2021 15:16:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:13
DataPoint Verified.		16 Apr 2021 16:10:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '14 Mar 2021'	(b) (4) Thea Marie Cordero	27 Mar 2021 00:37:37
	(b) (4)	

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Jun 2021 15:16:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:13
DataPoint Verified.		16 Apr 2021 16:10:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'CYSTOSCOPY'	(b) (4) Thea Marie Cordero (b) (4)	27 Mar 2021 00:37:37

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:13
DataPoint Verified.		16 Apr 2021 16:10:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered 'Adverse Event (AE)'	Thea Marie Cordero	27 Mar 2021 00:37:37
	(b) (4)	

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 11 Jun 2021 15:16:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:13
DataPoint Verified.		16 Apr 2021 16:10:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4)	27 Mar 2021 00:37:37
	Thea Marie Cordero	
	(b) (4)	

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Jun 2021 15:16:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:17
DataPoint Verified.		16 Apr 2021 16:10:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '14 Mar 2021'	(b) (4) Thea Marie Cordero	27 Mar 2021 00:39:47
	(b) (4)	

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Jun 2021 15:16:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:17
DataPoint Verified.		16 Apr 2021 16:10:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'URETEROSCOPY'	(b) (4) Thea Marie Cordero	27 Mar 2021 00:39:47
	(b) (4)	

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:17
DataPoint Verified.		16 Apr 2021 16:10:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Adverse Event (AE)'	(b) (4) Thea Marie Cordero	27 Mar 2021 00:39:47
	(b) (4)	

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 11 Jun 2021 15:16:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:17
DataPoint Verified.		16 Apr 2021 16:10:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4)	27 Mar 2021 00:39:47
	Thea Marie Cordero	
	(b) (4)	

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Jun 2021 15:16:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:25
DataPoint Verified.		16 Apr 2021 16:10:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered '14 Mar 2021'	(b) (4) Thea Marie Cordero	27 Mar 2021 00:40:51
	(b) (4)	

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Jun 2021 15:16:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:25
DataPoint Verified.		16 Apr 2021 16:10:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'LASER LITHOTRIPSY'	(b) (4) Thea Marie Cordero (b) (4)	27 Mar 2021 00:40:51

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:25
DataPoint Verified.		16 Apr 2021 16:10:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'Adverse Event (AE)'	(b) (4) Thea Marie Cordero (b) (4)	27 Mar 2021 00:40:51

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 11 Jun 2021 15:16:15

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:27:25
DataPoint Verified.		16 Apr 2021 16:10:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered empty.	(b) (4)	27 Mar 2021 00:40:51
	Thea Marie Cordero	
	(b) (4)	

US3862099

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 11 Jun 2021 15:16:15**

**Procedure/Surgery date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered '11 Apr 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:26:36

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 11 Jun 2021 15:16:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered 'NONOBSTRUCTIVE RENAL CALCULI LEFT KIDNEY REMOVAL'	(b) (4), (b) (6)	20 Apr 2021 22:26:36

**US3862099**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:26:36

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 11 Jun 2021 15:16:15

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:26:36

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 11 Jun 2021 15:16:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered '19 Apr 2021'	(b) (4), (b) (6)	20 Apr 2021 22:27:30

**US3862099**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 11 Jun 2021 15:16:15**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered 'URETHRAL STENT REMOVAL'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:27:30

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 11 Jun 2021 15:16:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:27:30

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 11 Jun 2021 15:16:15

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:27:30

US3862099

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (8)**

**Generated On: 11 Jun 2021 15:16:15**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered '13 Apr 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:38:14

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 11 Jun 2021 15:16:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered 'CT OF THE ABDOMEN AND PELVIS'	(b) (4), (b) (6)	20 Apr 2021 22:38:14

**US3862099**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (8)**

**Generated On: 11 Jun 2021 15:16:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:38:14

US3862099

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 11 Jun 2021 15:16:15

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 22:38:14

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'USA-US121-2021-MRNA-1273-P301000006'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'Yes (Y)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'Yes (Y)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Jun 2021 15:16:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Jun 2021 15:16:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'Thea Marie'	System	18 Mar 2021 15:04:09

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Jun 2021 15:16:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'Cordero'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'Houston'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'TX'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered '77030'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:40:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
User entered 'US'	System	18 Mar 2021 15:04:45

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	26 Apr 2021 13:21:46
User entered '5'	System	21 Apr 2021 13:53:52
User entered '4'	System	07 Apr 2021 14:40:56
User entered '3'	System	29 Mar 2021 16:51:08
User entered '2'	System	29 Mar 2021 13:35:32
User entered '1'	System	18 Mar 2021 15:04:45

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'USA-US121-2021-MRNA-1273-P301000006'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'Yes (Y)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'Yes (Y)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Jun 2021 15:16:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'Thea Marie'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'Cordero'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'Houston'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'TX'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered '77030'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:40:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
User entered 'US'	System	18 Mar 2021 15:04:45

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	26 Apr 2021 13:21:46
User entered '5'	System	21 Apr 2021 13:53:52
User entered '4'	System	07 Apr 2021 14:40:56
User entered '3'	System	29 Mar 2021 16:51:08
User entered '2'	System	29 Mar 2021 13:35:32
User entered '1'	System	18 Mar 2021 15:04:45

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (1)**

**Generated On: 11 Jun 2021 15:16:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
User entered '18/Mar/2021 11:04'	System	18 Mar 2021 15:04:45

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 11 Jun 2021 15:16:15

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:40:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
User entered 'I'		18 Mar 2021 15:04:45

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'USA-US121-2021-MRNA-1273-P301000006'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'Yes (Y)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'Yes (Y)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Jun 2021 15:16:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Jun 2021 15:16:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'Thea Marie'	System	18 Mar 2021 15:04:09

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Jun 2021 15:16:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'Cordero'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'Houston'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'TX'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered '77030'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:40:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
User entered 'US'	System	18 Mar 2021 15:04:45

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	26 Apr 2021 13:21:46
User entered '5'	System	21 Apr 2021 13:53:52
User entered '4'	System	07 Apr 2021 14:40:56
User entered '3'	System	29 Mar 2021 16:51:08
User entered '2'	System	29 Mar 2021 13:35:32
User entered '1'	System	18 Mar 2021 15:04:45

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (2)**

**Generated On: 11 Jun 2021 15:16:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '29/Mar/2021 06:35'	System	29 Mar 2021 13:35:32

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 11 Jun 2021 15:16:15

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:40:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'I'	(b) (4), (b) (6)	29 Mar 2021 13:35:32

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'USA-US121-2021-MRNA-1273-P301000006'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'Yes (Y)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Jun 2021 15:16:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'Yes (Y)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Jun 2021 15:16:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'Thea Marie'	System	18 Mar 2021 15:04:09

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Jun 2021 15:16:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'Cordero'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'Houston'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'TX'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered '77030'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:40:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
User entered 'US'	(b) (4), (b) (6) System	18 Mar 2021 15:04:45

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	26 Apr 2021 13:21:46
User entered '5'	System	21 Apr 2021 13:53:52
User entered '4'	System	07 Apr 2021 14:40:56
User entered '3'	System	29 Mar 2021 16:51:08
User entered '2'	System	29 Mar 2021 13:35:32
User entered '1'	System	18 Mar 2021 15:04:45

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (3)**

**Generated On: 11 Jun 2021 15:16:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
	(b) (4)	
User entered '29/Mar/2021 09:51'	System	29 Mar 2021 16:51:08

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 11 Jun 2021 15:16:15

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:40:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
User entered 'I'	(b) (4), (b) (6)	29 Mar 2021 16:51:08

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'USA-US121-2021-MRNA-1273-P301000006'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'Yes (Y)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'Yes (Y)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Jun 2021 15:16:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Jun 2021 15:16:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Jun 2021 15:16:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'Thea Marie'	System	18 Mar 2021 15:04:09

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Jun 2021 15:16:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'Cordero'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'Houston'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'TX'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered '77030'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:40:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
User entered 'US'	(b) (4), (b) (6) System	18 Mar 2021 15:04:45

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	26 Apr 2021 13:21:46
User entered '5'	System	21 Apr 2021 13:53:52
User entered '4'	System	07 Apr 2021 14:40:56
User entered '3'	System	29 Mar 2021 16:51:08
User entered '2'	System	29 Mar 2021 13:35:32
User entered '1'	System	18 Mar 2021 15:04:45

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (4)**

**Generated On: 11 Jun 2021 15:16:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:34:31
User entered '07/Apr/2021 09:40'	(b) (4) System	07 Apr 2021 14:40:56

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 11 Jun 2021 15:16:15

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 13:53:40
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:34:31
User entered 'I'	(b) (4), (b) (6)	07 Apr 2021 14:40:56

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'USA-US121-2021-MRNA-1273-P301000006'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'Yes (Y)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'Yes (Y)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Jun 2021 15:16:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'Thea Marie'	System	18 Mar 2021 15:04:09

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Jun 2021 15:16:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'Cordero'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'Houston'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'TX'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered '77030'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:40:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
User entered 'US'	System	18 Mar 2021 15:04:45

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	26 Apr 2021 13:21:46
User entered '5'	System	21 Apr 2021 13:53:52
User entered '4'	System	07 Apr 2021 14:40:56
User entered '3'	System	29 Mar 2021 16:51:08
User entered '2'	System	29 Mar 2021 13:35:32
User entered '1'	System	18 Mar 2021 15:04:45

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (5)**

**Generated On: 11 Jun 2021 15:16:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
	(b) (4)	
User entered '21/Apr/2021 09:53'	System	21 Apr 2021 13:53:52

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 11 Jun 2021 15:16:15

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 13:21:35
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:00:54
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 13:53:52

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'USA-US121-2021-MRNA-1273-P301000006'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'Yes (Y)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'Yes (Y)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 11 Jun 2021 15:16:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'No (N)'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'Thea Marie'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'Cordero'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
Reviewed for Safety.		18 Mar 2021 15:04:30
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'Houston'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered 'TX'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4)	18 Mar 2021 17:44:30
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 15:04:30
User entered '77030'	System	18 Mar 2021 15:04:09

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:40:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:20:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 17:44:30
User entered 'US'	System	18 Mar 2021 15:04:45

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form**

**Generated On: 11 Jun 2021 15:16:15**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	26 Apr 2021 13:21:46
User entered '5'	System	21 Apr 2021 13:53:52
User entered '4'	System	07 Apr 2021 14:40:56
User entered '3'	System	29 Mar 2021 16:51:08
User entered '2'	System	29 Mar 2021 13:35:32
User entered '1'	System	18 Mar 2021 15:04:45

**US3862099**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000006**

**Form: Safety Report Form (6)**

**Generated On: 11 Jun 2021 15:16:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
	(b) (4)	
User entered '26/Apr/2021 08:21'	System	26 Apr 2021 13:21:46

US3862099

Folder: SAE USA-US121-2021-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 11 Jun 2021 15:16:15

**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.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:03
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 13:21:46