

US3862144 (Prod: Baylor College of Medicine)

Generated By: KC Joubran

Generated On: 10 Jun 2021 10:02:10

All time stamps listed in this document are displayed in GMT

US3862144

Form: Participant Creation

Data signed: (b) (4) 02 Apr 2021 14:27:24

Generated On: 10 Jun 2021 10:02:10

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Participant ID

US3862144

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

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US3862144

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Date of Birth (MMM yyyy)	(b) (6) 1966
Age	53
Age Units	YEARS
Age (Derived)	53
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	True
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Date of Informed Consent (*dd MMM yyyy*) 08 SEP 2020

Month and Year of Informed Consent (derived) SEP 2020

Year of Informed Consent (derived) 2020

Protocol Version

Amendment 1	<input type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input checked="" type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify \_\_\_\_\_

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number \_\_\_\_\_

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

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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 00:53:03

Generated On: 10 Jun 2021 10:02:10

Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Condition	HIGH BLOOD PRESSURE
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: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Condition	S/P PNEUMOCYSTIS
Start date (dd MMM yyyy)	UN AUG 1999
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN AUG 2000
Stop date completely unknown	False
Start Month and Year (derived)	AUG 1999
Start Year (derived)	1999
Stop Month and Year (derived)	AUG 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Condition	HUMAN IMMUNODEFICIENCY VIRUS
Start date (dd MMM yyyy)	UN AUG 1999
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)	AUG 1999
Start Year (derived)	1999
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Condition	OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Condition	PERIPHEAL NEUROPATHY
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Condition	CHRONIC BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Condition	B12 DEFICIENCY
Start date (dd MMM yyyy)	UN UNK 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2018
Start Year (derived)	2018
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Condition	RECURRENT PERIANAL ABSCESS
Start date (dd MMM yyyy)	UN MAY 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	



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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	8 SEP 2020
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 12:40
Height (xxx.x)	67.0 in
Weight (xxx.x)	234.6 lb
BMI (xxx.x)	36.82038 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	098.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	082 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	083 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 00:53:03

Generated On: 10 Jun 2021 10:02:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

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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 00:53:03

Generated On: 10 Jun 2021 10:02:10

<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)	True
<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)	False
<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 00:53:22

Generated On: 10 Jun 2021 10:02:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:53:22

Generated On: 10 Jun 2021 10:02:10

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

What was the participant's randomization number? 145932

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 00:53:22

Generated On: 10 Jun 2021 10:02:10

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 00:53:22

Generated On: 10 Jun 2021 10:02:10

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)	8 SEP 2020
Time of assessment (00:00-23:59)	12:40 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 12:40
Temperature (xxx.x)	098.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	082 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	083 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 00:53:22

Generated On: 10 Jun 2021 10:02:10

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)	8 SEP 2020
Time of assessment (00:00-23:59)	16:14 (24 HR)
Vital Signs Date and Time (derived)	8 SEP 2020 16:14
Temperature (xxx.x)	096.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	079 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	087 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 00:53:22

Generated On: 10 Jun 2021 10:02:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 SEP 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐  
Physician withheld dose due to Adverse Event ☐  
Death ☐  
Lost To Follow-Up ☐  
Physician Decision ☐  
Pregnancy ☐  
Protocol Deviation ☐  
Study Terminated by Sponsor ☐  
Withdrawal of Consent by Participant ☐  
Confirmed COVID-19 ☐  
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 15:37 (24 HR)

Treatment Date and Time (derived) 08 SEP 2020 15:37

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:53:22

Generated On: 10 Jun 2021 10:02:10

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

Collection date (dd MMM yyyy)	08 SEP 2020
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Collection time (00:00-23:59)	14:39 (24 HR)
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Collection date and time (derived)	08 SEP 2020 14:39
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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Collection date (dd MMM yyyy)			08 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:25	08 SEP 2020 13:25
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

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: 10 Jun 2021 10:02:10

**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

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 15:58

PC Open Date & Time

08 SEP 2020 15:57

PC Close Date & Time

08 SEP 2020 18:27

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

**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 96.4 °F

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

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

PC Time Stamp	08 SEP 2020 19:27
PC Open Date & Time	08 SEP 2020 19:22
PC Close Date & Time	09 SEP 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

09 SEP 2020 12:06

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:10

**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

96.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 SEP 2020 12:09

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:10

**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

97.9 °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

11 SEP 2020 14:04

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °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

12 SEP 2020 12:01

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 12:01

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

14 SEP 2020 12:03

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 15:59

PC Open Date & Time

08 SEP 2020 15:57

PC Close Date & Time

08 SEP 2020 18:27

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 SEP 2020 19:28

PC Open Date & Time

08 SEP 2020 19:22

PC Close Date & Time

09 SEP 2020 11:59



US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 SEP 2020 12:07

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 SEP 2020 12:09

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 SEP 2020 14:04

PC Open Date & Time

11 SEP 2020 12:00

PC Close Date & Time

12 SEP 2020 11:59

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

12 SEP 2020 12:01

PC Open Date & Time

12 SEP 2020 12:00

PC Close Date & Time

13 SEP 2020 11:59

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 SEP 2020 12:01

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 SEP 2020 12:03

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

**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 ☐

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 15:59
PC Open Date & Time	08 SEP 2020 15:57
PC Close Date & Time	08 SEP 2020 18:27



US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

**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 ☐

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

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

No ☒

Yes ☐

PC Time stamp	08 SEP 2020 19:28
PC Open Date & Time	08 SEP 2020 19:22
PC Close Date & Time	09 SEP 2020 11:59

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:10

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 2430

EAB) (1725)

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:10

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 12:08
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:10

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2430

EAB) (1725)

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:10

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

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 4

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

54 of 2430

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:10

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



US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:10

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 ☒

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:10

Yes <input type="checkbox"/>	
PC Time stamp	12 SEP 2020 12:02
PC Open Date & Time	12 SEP 2020 12:00
PC Close Date & Time	13 SEP 2020 11:59

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:10

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

58 of 2430

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:10

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 12:02
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:10

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

60 of 2430

EAB) (1725)

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:10

Yes <input type="checkbox"/>	
PC Time stamp	14 SEP 2020 12:03
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3862144

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3862144

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3862144

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 22 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3862144

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862144

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 SEP 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3862144

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862144

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:53:22

Generated On: 10 Jun 2021 10:02:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3862144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:53:22

Generated On: 10 Jun 2021 10:02:10

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)	7 OCT 2020
Time of assessment (00:00-23:59)	09:00 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 09:00
Temperature (xxx.x)	097.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	078 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	127 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	091 mmHg
Diastolic Blood Pressure units	MMHG

US3862144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:53:22

Generated On: 10 Jun 2021 10:02:10

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)	7 OCT 2020
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	7 OCT 2020 10:25
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)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3862144

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:53:22

Generated On: 10 Jun 2021 10:02:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 OCT 2020

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



US3862144

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:53:22

Generated On: 10 Jun 2021 10:02:10

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) 7 OCT 2020

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

Treatment Date and Time (derived) 7 OCT 2020 09:53

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

What was the frequency of the study treatment dosing? ONCE

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

US3862144

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:53:22

Generated On: 10 Jun 2021 10:02:10

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

Collection date (dd MMM yyyy)	7 OCT 2020
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Collection time (00:00-23:59)	09:20 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	7 OCT 2020 09:20
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US3862144

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:53:22

Generated On: 10 Jun 2021 10:02:10

Collection date (dd MMM yyyy)			7 OCT 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	09:14	7 OCT 2020 09:14

US3862144

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:53:22

Generated On: 10 Jun 2021 10:02:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

**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

07 OCT 2020 10:25

PC Open Date & Time

07 OCT 2020 10:13

PC Close Date & Time

07 OCT 2020 12:43

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	07 OCT 2020 13:40
PC Open Date & Time	07 OCT 2020 13:38
PC Close Date & Time	08 OCT 2020 11:59

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 12:02

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:10

**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

09 OCT 2020 12:02

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59



US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:10

**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

10 OCT 2020 13:21

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 12:28

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:10

**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

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

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:10

**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.

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

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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

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

**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

07 OCT 2020 10:25

PC Open Date & Time

07 OCT 2020 10:13

PC Close Date & Time

07 OCT 2020 12:43

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

**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

07 OCT 2020 13:40

PC Open Date & Time

07 OCT 2020 13:38

PC Close Date & Time

08 OCT 2020 11:59

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:10

**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

08 OCT 2020 12:02

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:10

**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

09 OCT 2020 12:03

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59



US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:10

**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

10 OCT 2020 13:22

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:10

**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

11 OCT 2020 12:28

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:10

**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 ☐

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

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:10

**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

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

**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 ☐

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 10:26
PC Open Date & Time	07 OCT 2020 10:13
PC Close Date & Time	07 OCT 2020 12:43

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

**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 ☐

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

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

No ☒

Yes ☐

PC Time stamp	07 OCT 2020 13:41
PC Open Date & Time	07 OCT 2020 13:38
PC Close Date & Time	08 OCT 2020 11:59



US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:10

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 ☒

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:10

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 12:03
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:10

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:10

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 12:03
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:10

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 ☒

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:10

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 13:23
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:10

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:10

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



US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:10

Yes ☐

PC Time stamp

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☐

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☐

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:10

Yes ☐

PC Time stamp

PC Open Date & Time

13 OCT 2020 12:00

PC Close Date & Time

14 OCT 2020 11:59

US3862144

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:31:27

Generated On: 10 Jun 2021 10:02:10

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3862144

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:31:27

Generated On: 10 Jun 2021 10:02:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862144

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 OCT 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3862144

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3862144

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3862144

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:53:03

Generated On: 10 Jun 2021 10:02:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862144

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:53:22

Generated On: 10 Jun 2021 10:02:10

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

US3862144

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:53:22

Generated On: 10 Jun 2021 10:02:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	5 NOV 2020
Time of assessment (00:00-23:59)	08:30 (24 HR)
Vital Signs Date and Time (derived)	5 NOV 2020 08:30
Temperature (xxx.x)	097.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	083 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	099 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862144

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:53:22

Generated On: 10 Jun 2021 10:02:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 NOV 2020

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

US3862144

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:53:22

Generated On: 10 Jun 2021 10:02:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 NOV 2020
Collection time (00:00-23:59)	09:40 (24 HR)
Collection date and time (derived)	5 NOV 2020 09:40

US3862144

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:53:22

Generated On: 10 Jun 2021 10:02:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862144

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3862144

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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23 NOV 2020 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 20:47:54
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 DEC 2020 00:02:11

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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 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 DEC 2020 09:40:35
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59



US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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

17 DEC 2020 00:02:16

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 DEC 2020 00:02:46

Patient Cloud Open Date & Time

24 DEC 2020 00:01

Patient Cloud Close Date & Time

28 DEC 2020 23:59

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 00:15:27

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 JAN 2021 00:02:23
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 08:54:02
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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

25 JAN 2021 12:52:38

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 12:01:03

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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

04 FEB 2021 09:18:55

Patient Cloud Open Date & Time

04 FEB 2021 00:01

Patient Cloud Close Date & Time

08 FEB 2021 23:59



US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 159

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

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

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

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

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

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

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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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15 FEB 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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22 FEB 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 173

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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01 MAR 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

04 MAR 2021 00:01

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[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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

15 MAR 2021 16:31:47

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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

19 MAR 2021 01:24:15

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 09:49:29

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 00:24:12

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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

08 APR 2021 08:08:57

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 00:02:33

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 00:40:35

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 APR 2021 06:01:31

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59



US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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10 MAY 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Open Date & Time](#)

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13 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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17 MAY 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Open Date & Time](#)

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20 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAY 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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31 MAY 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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10 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUN 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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21 JUN 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59



US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Open Date & Time](#)

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08 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 JUL 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2021 23:59

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 JUL 2021 23:59



US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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02 AUG 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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09 AUG 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	12 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59
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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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23 AUG 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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30 AUG 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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06 SEP 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Open Date & Time](#)

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09 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 SEP 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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20 SEP 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 390

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

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

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

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

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

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

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

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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04 OCT 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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11 OCT 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	14 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 OCT 2021 23:59



US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Open Date & Time](#)

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28 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 NOV 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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08 NOV 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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15 NOV 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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22 NOV 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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29 NOV 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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06 DEC 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 DEC 2021 23:59



US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

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

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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20 DEC 2021 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 474

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

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

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

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

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

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

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

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	23 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2021 23:59
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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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03 JAN 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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="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"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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10 JAN 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Open Date & Time](#)

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13 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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17 JAN 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Open Date & Time](#)

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20 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 JAN 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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31 JAN 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

10 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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21 FEB 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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24 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 FEB 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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07 MAR 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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10 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 MAR 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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21 MAR 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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24 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 MAR 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Open Date & Time](#)

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31 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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04 APR 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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11 APR 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

TIMEPOINT	DAY 586
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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18 APR 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 APR 2022 23:59

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Open Date & Time](#)

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28 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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02 MAY 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Open Date & Time](#)

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05 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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09 MAY 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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16 MAY 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Open Date & Time](#)

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19 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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23 MAY 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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30 MAY 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Open Date & Time](#)

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09 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JUN 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Open Date & Time](#)

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16 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JUN 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59



US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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 <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"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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04 JUL 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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11 JUL 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Open Date & Time](#)

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21 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 JUL 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Open Date & Time](#)

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28 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 AUG 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Open Date & Time](#)

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04 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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08 AUG 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	11 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	15 AUG 2022 23:59
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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

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22 AUG 2022 23:59



US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2022 23:59
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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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05 SEP 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

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

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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"/>

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

15 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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26 SEP 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Open Date & Time](#)

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29 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 OCT 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Close Date & Time](#)

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10 OCT 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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



US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Open Date & Time](#)

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20 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 OCT 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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>	27 OCT 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	31 OCT 2022 23:59
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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

**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 ☐

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

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[Patient Cloud Open Date & Time](#)

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03 NOV 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 NOV 2022 23:59

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US3862144

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 10:02:10

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

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	14 NOV 2022 23:59
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**US3862144**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 10 Jun 2021 10:02:10**

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		15 MAR 2021 16:32:05

US3862144

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 05 Mar 2021 22:31:27

Generated On: 10 Jun 2021 10:02:10

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 DEC 2020

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

Comments

*If Contact Not Made, please provide Comments*

US3862144

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 05 Mar 2021 22:31:27

Generated On: 10 Jun 2021 10:02:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862144

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:27:27

Generated On: 10 Jun 2021 10:02:10

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 JAN 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3862144

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:27:27

Generated On: 10 Jun 2021 10:02:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862144

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:27:27

Generated On: 10 Jun 2021 10:02:10

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*

US3862144

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:27:27

Generated On: 10 Jun 2021 10:02:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862144

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:27:27

Generated On: 10 Jun 2021 10:02:10

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*



US3862144

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:27:27

Generated On: 10 Jun 2021 10:02:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862144

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 18:36:06

Generated On: 10 Jun 2021 10:02:10

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

Visit date (dd MMM yyyy)	05 APR 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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US3862144

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 18:36:06

Generated On: 10 Jun 2021 10:02:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 APR 2021
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	05 APR 2021 09:05
Temperature (xxx.x)	97.4 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)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862144

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 18:36:06

Generated On: 10 Jun 2021 10:02:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 APR 2021

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

US3862144

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 18:36:06

Generated On: 10 Jun 2021 10:02:10

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

05 APR 2021

Collection time (00:00-23:59)

09:39 (24 HR)

Collection date and time (derived)

05 APR 2021 09:39

US3862144

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 18:36:06

Generated On: 10 Jun 2021 10:02:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3862144**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

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*

**US3862144**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag



US3862144

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 02 Apr 2021 14:27:26

Generated On: 10 Jun 2021 10:02:10

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[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☐

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US3862144

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

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:27:26

Generated On: 10 Jun 2021 10:02:10

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

Visit date (dd MMM yyyy)	25 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"/>

Folder OID	UNBLND_DECIDE
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US3862144

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

Form: Unblinding

Data signed: (b) (4) 02 Apr 2021 14:27:26

Generated On: 10 Jun 2021 10:02:10

Date of updated informed consent (dd MMM yyyy)	25 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 (dd MMM yyyy)	25 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

US3862144

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 02 Apr 2021 14:27:26

Generated On: 10 Jun 2021 10:02:10

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

US3862144

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 14:27:26

Generated On: 10 Jun 2021 10:02:10

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)	25 JAN 2021
Time of assessment (00:00-23:59)	11:48 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 11:48
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	100 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3862144

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 14:27:26

Generated On: 10 Jun 2021 10:02:10

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)	25 JAN 2021
Time of assessment (00:00-23:59)	13:32 (24 HR)
Vital Signs Date and Time (derived)	25 JAN 2021 13:32
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input type="radio"/> Axillary <input type="radio"/> Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	91 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3862144

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

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:27:26

Generated On: 10 Jun 2021 10:02:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 JAN 2021

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

US3862144

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

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 14:27:26

Generated On: 10 Jun 2021 10:02:10

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) 25 JAN 2021

What was the treatment time? (00:00-23:59) 13:02 (24 HR)

Treatment Date and Time (derived) 25 JAN 2021 13:02

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



US3862144

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 02 Apr 2021 14:27:26

Generated On: 10 Jun 2021 10:02:10

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

Collection date (dd MMM yyyy)	25 JAN 2021
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Collection time (00:00-23:59)	11:56 (24 HR)
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Collection date and time (derived)	25 JAN 2021 11:56
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US3862144

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 02 Apr 2021 14:27:26

Generated On: 10 Jun 2021 10:02:10

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 JAN 2021
Collection time (00:00 - 23:59)	11:53
Collection Date and Time (derived)	25 JAN 2021 11:53

US3862144

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

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:27:26

Generated On: 10 Jun 2021 10:02:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862144

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:27:27

Generated On: 10 Jun 2021 10:02:10

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 FEB 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3862144

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:27:27

Generated On: 10 Jun 2021 10:02:10

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

US3862144

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 02 Apr 2021 14:27:26

Generated On: 10 Jun 2021 10:02:10

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

Visit date (dd MMM yyyy)	01 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	OLD29
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US3862144

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 02 Apr 2021 14:27:26

Generated On: 10 Jun 2021 10:02:10

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)	1 MAR 2021
Time of assessment (00:00-23:59)	10:01 (24 HR)
Vital Signs Date and Time (derived)	1 MAR 2021 10:01
Temperature (xxx.x)	097.9 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	068 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	012 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	093 mmHg
Diastolic Blood Pressure units	MMHG

US3862144

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 02 Apr 2021 14:27:26

Generated On: 10 Jun 2021 10:02:10

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)	1 MAR 2021
Time of assessment (00:00-23:59)	11:30 (24 HR)
Vital Signs Date and Time (derived)	1 MAR 2021 11:30
Temperature (xxx.x)	097.6 F
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	TEMPORAL
Pulse (xxx)	074 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	012 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	095 mmHg
Diastolic Blood Pressure units	MMHG



US3862144

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 02 Apr 2021 14:27:26

Generated On: 10 Jun 2021 10:02:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 MAR 2021

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

US3862144

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 02 Apr 2021 14:27:26

Generated On: 10 Jun 2021 10:02:10

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) 1 MAR 2021

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

Treatment Date and Time (derived) 1 MAR 2021 11:00

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

US3862144

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:27:26

Generated On: 10 Jun 2021 10:02:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862144

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 02 Apr 2021 14:27:27

Generated On: 10 Jun 2021 10:02:10

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 8 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3862144

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 02 Apr 2021 14:27:27

Generated On: 10 Jun 2021 10:02:10

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3862144

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 18:36:06

Generated On: 10 Jun 2021 10:02:10

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3862144

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 18:36:06

Generated On: 10 Jun 2021 10:02:10

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	05 APR 2021
Time of assessment (00:00-23:59)	09:05 (24 HR)
Vital Signs Date and Time (derived)	05 APR 2021 09:05
Temperature (xxx.x)	97.4 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)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	119 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3862144

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 18:36:06

Generated On: 10 Jun 2021 10:02:10

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 APR 2021

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



US3862144

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 18:36:06

Generated On: 10 Jun 2021 10:02:10

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

Collection date (dd MMM yyyy)	05 APR 2021
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Collection time (00:00-23:59)	09:39 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	05 APR 2021 09:39
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US3862144

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Mar 2021 15:17:36

Generated On: 10 Jun 2021 10:02:10

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3862144

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:10

AEID	
Adverse event	PERIRECTAL ABSCESS
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)	4 NOV 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)	2 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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EAB) (1725)

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US3862144

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:10

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 _____	
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) _____	

US3862144

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:10

AEID	
Adverse event	ANAL FISTULA
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)	02 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)	03 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:10

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 _____	
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 (3)

Generated On: 10 Jun 2021 10:02:10

AEID	USA-US121-2021-MRNA-1273-P30 1000003
Adverse event	PARTIAL BOWEL OBSTRUCTION
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)	19 FEB 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)	24 FEB 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)	21 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	24 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:10

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input 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	SUBJECT HOSPITALIZED FROM 21 FEB 2021- 24 FEB 2021, DIAGNOSIS PARTIAL BOWEL OBSTRUCTION. MANAGED CONSERVATIVELY WITH PAIN MEDICAITONS, ANTI-EMETICS AND WAS KEPT NPO.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

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0

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 02 Apr 2021 14:27:25

Generated On: 10 Jun 2021 10:02:10

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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.

---

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

Name of Medication AMLODIPINE

Prophylaxis Yes ☐  
No ☒

Indication HIGH BLOOD PRESSURE

Dose per administration 5

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

	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 2019	
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) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

Name of Medication HYDROCHLOROTHIAZIDE

Prophylaxis Yes ☐  
No ☒

Indication HIGH BLOOD PRESSURE

Dose per administration 25

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) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

	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 2019	
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) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

Name of Medication HYDROCODONE  
ACETAMINOPHEN

Prophylaxis Yes ☐  
No ☒

Indication CHRONIC BACK PAIN

Dose per administration 10-325

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☒  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

	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)	UN UNK 2010	
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)	4	
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) 15 Apr 2021 21:43:10

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Name of Medication PREGABALIN

Prophylaxis Yes ☐  
No ☒

Indication PERIPHERAL NEUROPATHY

Dose per administration 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

	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 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)	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 (5)

Data signed: (b) (4) 15 Apr 2021 21:43:10

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Name of Medication ODEFSEY

Prophylaxis Yes ☐  
No ☒

Indication HUMAN IMMUNODEFICIENCY  
VIRUS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 15 Apr 2021 21:43:10

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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)	UN UNK 2019	
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 (6)

Data signed: (b) (4) 15 Apr 2021 21:43:10

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Name of Medication VITAMIN B12

Prophylaxis Yes ☐  
No ☒

Indication B12 DEFICIENCY

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 (6)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

	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 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 (7)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PREVENTION

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 (7)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		23 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐  
No ☒

Indication PERIRECTAL ABSCESS

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 (8)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

	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)	6 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 NOV 2020
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 (9)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐  
No ☒

Indication PERIRECTAL ABSCESS

Dose per administration 500

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

	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)	6 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 15 NOV 2020		
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐  
No ☒

Indication PERIRECTAL ABSCESS

Dose per administration 500

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☒  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

	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)	6 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 NOV 2020
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 (11)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

Name of Medication IBUPROFEN

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXES FOR RECTAL  
PAIN FOR SETON PLACEMENT

Dose per administration 800

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☒

If frequency is Other, specify

EVERY 8 HOURS PRN

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) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

	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)	03 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)		28 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 (12)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

Name of Medication GABAPENTIN

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXES FOR RECTAL  
PAIN FOR SETON PLACEMENT

Dose per administration 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

	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)	03 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)	28 FEB 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 (13)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

Name of Medication GAVILAX

Prophylaxis Yes ☒  
No ☐

Indication PROPHYLAXES FOR RECTAL  
PAIN FOR SETON PLACEMENT

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 ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

	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)	03 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)	28 FEB 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 (14)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

Name of Medication SPRING VALLEY PROBIOTIC

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

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 (14)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	24 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	01 MAR 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

Name of Medication MORPHINE SULFATE

Prophylaxis Yes ☐  
No ☒

Indication SAE#3 PARTIAL SMALL BOWEL OBSTRUCTION

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 (16)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	21 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)		22 FEB 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"/>



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

Name of Medication ONDANSETRON

Prophylaxis Yes ☐  
No ☒

Indication SAE#3 PARTIAL SMALL BOWEL  
OBSTRUCTION

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 (17)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

	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)	21 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)		21 FEB 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 (18)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐  
No ☒

Indication SAE#3 PARTIAL SMALL BOWEL  
OBSTRUCTION

Dose per administration 100

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify ML/HOUR

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 ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

	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 checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	21 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)		21 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 (19)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

Name of Medication MORPHINE SULFATE

Prophylaxis Yes ☐  
No ☒

Indication SAE#3 PARTIAL SMALL BOWEL OBSTRUCTION

Dose per administration 2

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 (19)

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

	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 checked="" type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	22 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		22 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 02 Apr 2021 14:27:26

Generated On: 10 Jun 2021 10:02:10

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 15 Apr 2021 21:43:10

Generated On: 10 Jun 2021 10:02:10

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
02 DEC 2020	COLONOSCOPY	Adverse Event	
22 JAN 2021	MRI	Adverse Event	
03 FEB 2021	SETON PLACEMENT	Adverse Event	
21 FEB 2021	ELECTROCARDIOGRAM	Adverse Event	
21 FEB 2021	CT ABDOMEN AND PELVIS	Adverse Event	
22 FEB 2021	NGT PLACEMENT	Adverse Event	
22 FEB 2021	ABDOMINAL X-RAY	Adverse Event	
22 FEB 2021	NGT REMOVAL	Adverse Event	



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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 10:02:10

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent  
by participant, Protocol deviation, or Other, specify

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 10:02:10

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 ☐

US3862144

Folder: SAE USA-US121-2021-MRNA-1273-P301000003

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 22:04:15

Generated On: 10 Jun 2021 10:02:10

SAEID	USA-US121-2021-MRNA-1273-P301000003
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)	5

US3862144

Folder: SAE USA-US121-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 22:04:15

Generated On: 10 Jun 2021 10:02:10

SAEID	USA-US121-2021-MRNA-1273-P301000003
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)	5
Date of submission (Pre-filled from custom function)	01/MAR/2021 10:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3862144

Folder: SAE USA-US121-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 22:04:15

Generated On: 10 Jun 2021 10:02:10

SAEID	USA-US121-2021-MRNA-1273-P301000003
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)	5
Date of submission (Pre-filled from custom function)	29/MAR/2021 06:34
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3862144

Folder: SAE USA-US121-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 22:04:15

Generated On: 10 Jun 2021 10:02:10

SAEID	USA-US121-2021-MRNA-1273-P301000003
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)	5
Date of submission (Pre-filled from custom function)	14/APR/2021 10:26
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

US3862144

Folder: SAE USA-US121-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 22:04:15

Generated On: 10 Jun 2021 10:02:10

SAEID	USA-US121-2021-MRNA-1273-P301000003
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)	5
Date of submission (Pre-filled from custom function)	16/APR/2021 08:47
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

US3862144

Folder: SAE USA-US121-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 22:04:15

Generated On: 10 Jun 2021 10:02:10

SAEID	USA-US121-2021-MRNA-1273-P301000003
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)	5
Date of submission (Pre-filled from custom function)	26/APR/2021 14:29
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

US3862144 (Prod: Baylor College of Medicine)

**US3862144**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 10:02:10**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
User entered 'US3862144'	RWS_ENDPOINT	08 Sep 2020 18:04:33
	ENDPOINT (b) (4)	
	(b) (4)	

**US3862144**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:40:53

US3862144

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:02:10

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '08 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 18:04:34

US3862144

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 10:02:10

[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 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Clinic (Clinic)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 20:40:53

**US3862144**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered 'SCRN'	System	08 Sep 2020 20:40:53

US3862144

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 10:02:10

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered (b) (6) 1966'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 18:04:35

**US3862144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:02:10**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '53'	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:41:41



**US3862144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:02:10**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered 'YEARS'	System	08 Sep 2020 20:41:41

**US3862144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:02:10**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered '53'	System	08 Sep 2020 20:42:01

**US3862144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:02:10**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Male (M)'	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:41:41

**US3862144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:02:10**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:41:41

**US3862144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:02:10**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '1' reason for change: Data Entry Error	(b) (4)	10 Oct 2020 23:41:19
User entered '0'	Coni Cheesman (b) (4)	08 Sep 2020 20:41:41
	(b) (4)	
	Sandra Francisco (b) (4)	
	(b) (4)	

**US3862144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:02:10**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'I'	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:41:41

**US3862144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:02:10**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:41:41

**US3862144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:02:10**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:41:41



**US3862144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:02:10**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:41:41

**US3862144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:02:10**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:41:41

**US3862144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:02:10**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:41:41

**US3862144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:02:10**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:41:41

**US3862144**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 10:02:10**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:41:41

US3862144

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 10:02:10

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '08 Sep 2020'	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:42:01

**US3862144**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:02:10**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered 'Sep 2020'	System	08 Sep 2020 20:42:01

**US3862144**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:02:10**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered '2020'	System	08 Sep 2020 20:42:01



**US3862144**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:02:10**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Amendment 3 (3)'	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:42:01

**US3862144**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:02:10**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:42:01

**US3862144**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:02:10**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:42:01

**US3862144**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:02:10**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:42:01

**US3862144**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:02:10**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'No (N)'	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:42:01

**US3862144**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:02:10**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 18:04:34

**US3862144**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 10:02:10**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered 'I'	System	08 Sep 2020 20:42:06

**US3862144**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 10:02:10**

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:42:06



**US3862144**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 10:02:10**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:48:05

US3862144

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 10:02:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Blood pressure high - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:49:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:49:40
Data point term sent to Coder	System	11 Sep 2020 18:48:54
User entered 'High Blood PResure'	Trent Davis (b) (4)	11 Sep 2020 18:48:30
	(b) (4)	

**US3862144**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'un UNK 2000'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:48:30

**US3862144**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	Trent Davis (b) (4)	11 Sep 2020 18:48:30

**US3862144**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:48:30

**US3862144**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:02:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:48:30

**US3862144**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:48:30

**US3862144**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered 'Jan 2000'	System	11 Sep 2020 18:48:30



**US3862144**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered '2000'	System	11 Sep 2020 18:48:30

**US3862144**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered empty.	System	11 Sep 2020 18:48:30

**US3862144**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered empty.	System	11 Sep 2020 18:48:30

US3862144

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 10:02:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Pneumocystis infections, PT: Pneumocystis jirovecii infection, LLT: Pneumocystis jirovecii infection - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 09:10:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Oct 2020 09:10:23
Data point term sent to Coder	System	11 Sep 2020 18:51:04
User entered 'S/P Pneumocystis'	Trent Davis (b) (4)	11 Sep 2020 18:50:49

**US3862144**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'un Aug 1999'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:50:49

**US3862144**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:50:49

**US3862144**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:50:49

**US3862144**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:02:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'un Aug 2000'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:50:49



**US3862144**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 18:50:49

**US3862144**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered 'Aug 1999'	System	11 Sep 2020 18:50:49

**US3862144**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered '1999'	System	11 Sep 2020 18:50:49

**US3862144**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered 'Aug 2000'	System	11 Sep 2020 18:50:49

**US3862144**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered '2000'	System	11 Sep 2020 18:50:49

US3862144

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 10:02:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Retroviral infections, PT: HIV infection, LLT: Human immunodeficiency virus syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:52:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:52:40
Data point term sent to Coder	System	11 Sep 2020 18:52:06
User entered 'human immunodeficiency virus'	Trent Davis (b) (4)	11 Sep 2020 18:51:26

**US3862144**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'un Aug 1999'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:51:26

**US3862144**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:51:26



**US3862144**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:51:26

**US3862144**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:02:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:51:26

**US3862144**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:51:26

**US3862144**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered 'Aug 1999'	System	11 Sep 2020 18:51:26

**US3862144**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered '1999'	System	11 Sep 2020 18:51:26

**US3862144**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered empty.	System	11 Sep 2020 18:51:26

**US3862144**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered empty.	System	11 Sep 2020 18:51:26

US3862144

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 10:02:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthritis, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:54:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:54:38
Data point term sent to Coder	System	11 Sep 2020 18:53:07
User entered 'OSteoArthritis'	Trent Davis (b) (4)	11 Sep 2020 18:52:09



**US3862144**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'un UNK 2010'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:52:09

**US3862144**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:52:09

**US3862144**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:52:09

**US3862144**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 10:02:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:52:09

**US3862144**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:52:09

**US3862144**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered 'Jan 2010'	System	11 Sep 2020 18:52:09

**US3862144**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered '2010'	System	11 Sep 2020 18:52:09

**US3862144**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered empty.	System	11 Sep 2020 18:52:09



**US3862144**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered empty.	System	11 Sep 2020 18:52:09

US3862144

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 10:02:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Peripheral neuropathies NEC, PT: Neuropathy peripheral, LLT: Peripheral neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 04:40:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Sep 2020 04:40:49
Data point term sent to Coder	System	11 Sep 2020 18:55:13
User entered 'PERipheal Neuropathy'	Trent Davis (b) (4)	11 Sep 2020 18:54:33

**US3862144**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'un UNK 2010'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:54:33

**US3862144**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:54:33

**US3862144**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:54:33

**US3862144**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 10:02:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:54:33

**US3862144**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:54:33

**US3862144**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered 'Jan 2010'	System	11 Sep 2020 18:54:33



**US3862144**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered '2010'	System	11 Sep 2020 18:54:33

**US3862144**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered empty.	System	11 Sep 2020 18:54:33

**US3862144**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered empty.	System	11 Sep 2020 18:54:33

US3862144

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 10:02:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
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: Back pain, LLT: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:56:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:56:20
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: Back pain, LLT: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:55:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:55:41
Data point term sent to Coder	System	11 Sep 2020 18:55:15
User entered 'Chronic Back PAin'	Trent Davis (b) (4)	11 Sep 2020 18:55:06

**US3862144**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'un UNK 2010'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:55:06

**US3862144**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:55:06

**US3862144**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 10:02:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:55:06

**US3862144**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 10:02:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:55:06



**US3862144**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:55:06

**US3862144**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 10:02:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered 'Jan 2010'	System	11 Sep 2020 18:55:06

**US3862144**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 10:02:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered '2010'	System	11 Sep 2020 18:55:06

**US3862144**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered empty.	System	11 Sep 2020 18:55:06

**US3862144**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered empty.	System	11 Sep 2020 18:55:06

US3862144

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 10:02:10

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Water soluble vitamin deficiencies, PT: Vitamin B12 deficiency, LLT: Vitamin B12 deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:57:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 18:57:43
Data point term sent to Coder	System	11 Sep 2020 18:56:16
User entered 'B12 Deficiency'	Trent Davis (b) (4)	11 Sep 2020 18:55:36
	(b) (4)	

**US3862144**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'un UNK 2018'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:55:36

**US3862144**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 18:55:36



**US3862144**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 10:02:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:55:36

**US3862144**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 10:02:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:55:36

**US3862144**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 18:55:36

**US3862144**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 10:02:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered 'Jan 2018'	System	11 Sep 2020 18:55:36

**US3862144**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 10:02:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered '2018'	System	11 Sep 2020 18:55:36

**US3862144**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered empty.	System	11 Sep 2020 18:55:36

**US3862144**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered empty.	System	11 Sep 2020 18:55:36

US3862144

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 10:02:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Oedema NEC, PT: Oedema peripheral, LLT: Edema of lower extremities - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 19:29:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	11 Sep 2020 19:29:44
Data point term sent to Coder	System	11 Sep 2020 19:03:39
User entered 'Edema Bilateral legs and ankles'	Trent Davis (b) (4)	11 Sep 2020 19:02:45



**US3862144**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'un UNK 2018'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:02:45

**US3862144**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:02:45

**US3862144**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 10:02:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:02:45

**US3862144**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 10:02:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:02:45

**US3862144**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:02:45

**US3862144**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 10:02:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered 'Jan 2018'	System	11 Sep 2020 19:02:45

**US3862144**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 10:02:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered '2018'	System	11 Sep 2020 19:02:45

**US3862144**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered empty.	System	11 Sep 2020 19:02:45



**US3862144**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered empty.	System	11 Sep 2020 19:02:45

US3862144

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 10:02:10

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Anal abscess, LLT: Perianal abscess - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 16:32:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 16:32:20
Data point term sent to Coder	System	05 Nov 2020 15:34:13
User entered 'recurrent perianal abscess'	Carrie Kibler (b) (4)	05 Nov 2020 15:34:01

**US3862144**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'un May 2020'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:34:01
	(b) (4)	

**US3862144**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:34:01

**US3862144**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 10:02:10**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:34:01

**US3862144**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 10:02:10**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:34:01
	(b) (4)	

**US3862144**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:34:01

**US3862144**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 10:02:10**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered 'May 2020'	System	05 Nov 2020 15:34:01



**US3862144**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 10:02:10**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered '2020'	System	05 Nov 2020 15:34:01

**US3862144**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered empty.	System	05 Nov 2020 15:34:01

**US3862144**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 10:02:10**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered empty.	System	05 Nov 2020 15:34:01

**US3862144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:05:13

**US3862144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '8 Sep 2020'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:05:13

**US3862144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '12:40'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:05:13

**US3862144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered '8 Sep 2020 12:40'	System	11 Sep 2020 19:05:13

US3862144

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:10

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '67.0' in	(b) (4)	
	Trent Davis (b) (4)	11 Sep 2020 19:05:13
DataPoint set to visible.	(b) (4)	
	System	08 Sep 2020 20:42:06



US3862144

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:10

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '234.6' lb	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:05:13
DataPoint set to visible.	(b) (4) System	08 Sep 2020 20:42:06

**US3862144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered '36.82038'	System	11 Sep 2020 19:05:13
DataPoint set to visible.	System	08 Sep 2020 20:42:06

**US3862144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered 'kg/m2'	System	11 Sep 2020 19:05:13
DataPoint set to visible.	System	08 Sep 2020 20:42:06

US3862144

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '098.3' F	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:05:13

**US3862144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Oral (Oral)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:05:13

**US3862144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:05:13

**US3862144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '082'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:05:13

**US3862144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered 'bpm'	System	11 Sep 2020 19:05:13



US3862144

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '016'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:05:13

**US3862144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered 'breaths/min'	System	11 Sep 2020 19:05:13

**US3862144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '119'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:05:13

**US3862144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered 'mmHg'	System	11 Sep 2020 19:05:13

US3862144

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '083'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:05:13

**US3862144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User entered 'mmHg'	System	11 Sep 2020 19:05:13

US3862144

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:10

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20

**US3862144**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20



**US3862144**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:02:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:46:34

**US3862144**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:02:10**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '08 Sep 2020'	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:46:34

US3862144

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:10

[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 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:03:33

US3862144

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:10

**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 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'No (N)'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:03:33

US3862144

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:10

**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 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'No (N)'	Trent Davis (b) (4)	11 Sep 2020 19:03:33

US3862144

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:10

**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 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'No (N)'	Trent Davis (b) (4)	11 Sep 2020 19:03:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:10

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 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:03:33

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Folder: Screening

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[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'No (N)'	Trent Davis (b) (4)	11 Sep 2020 19:03:33



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Folder: Screening

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**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'No (N)'	Trent Davis (b) (4)	11 Sep 2020 19:03:33

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Folder: Screening

Form: Risk of Exposure

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**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'No (N)'	Trent Davis (b) (4)	11 Sep 2020 19:03:33

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Folder: Screening

Form: Risk of Exposure

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:03:33

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Folder: Screening

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**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'No (N)'	Trent Davis (b) (4)	11 Sep 2020 19:03:33

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Folder: Screening

Form: Risk of Exposure

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**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'No (N)'	Trent Davis (b) (4)	11 Sep 2020 19:03:33

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**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 10:02:10**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:03:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:10

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:03:33

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:03:33



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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:10

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:03:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:10

**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 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	Trent Davis (b) (4)	11 Sep 2020 19:03:33

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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 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'I'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:03:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:10

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 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	Trent Davis (b) (4)	11 Sep 2020 19:03:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:10

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:03:33

US3862144

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:10

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '0'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:03:33

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 10:02:10

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 20:20:20
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:03:33

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 20:42:17



**US3862144**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '08 Sep 2020'	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:42:17

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[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 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Clinic (Clinic)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 20:42:17

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered 'VISIT1'	System	08 Sep 2020 20:42:17

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '08 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 20:19:19

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 10:02:10**

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '145932'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	08 Sep 2020 20:19:19

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:02:10

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	12 Nov 2020 14:09:48
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' answered with 'Risk is reported below as HIV.' (Site from DM).	Shetel Anassi (b) (4)	03 Nov 2020 19:05:26
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from DM).	(b) (4), (b) (6)	03 Nov 2020 18:12:42
Query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	03 Nov 2020 18:12:37
Amendment Manager: User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	30 Sep 2020 22:19:00
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	30 Sep 2020 22:19:00
Comment added 'Subject is at risk due to HIV positive'.	Chanei Henry (b) (4)	16 Sep 2020 23:45:24
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	11 Sep 2020 19:13:04
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Sep 2020 20:19:19

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 10:02:10

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 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'No (N)'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:13:04

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 10:02:10**

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 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'No (N)'	Trent Davis (b) (4)	11 Sep 2020 19:13:04



**US3862144**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 10:02:10**

[Severe obesity \(body mass index > or = 40kg/m2\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'No (N)'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:13:04

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 10:02:10**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:13:04

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 10:02:10**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:13:04

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 10:02:10**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	22 Sep 2020 18:49:21
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 05:41:08
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:41:07

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:02:10

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 15:12:28
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight accordingly.' answered with 'Data Corrected ' (Site from DM).	Shetel Anassi (b) (4)	20 Oct 2020 17:01:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Oct 2020 17:01:49
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:42:19
User entered empty.	Trent Davis (b) (4)	11 Sep 2020 19:09:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:02:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Oct 2020 17:01:49
User entered empty.	Shetel Anassi (b) (4)	11 Sep 2020 19:09:31
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:02:10

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 15:12:28
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight accordingly.' answered with 'Data Corrected ' (Site from DM).	Shetel Anassi (b) (4)	20 Oct 2020 17:01:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Oct 2020 17:01:49
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:42:19
User entered empty.	Trent Davis (b) (4)	11 Sep 2020 19:09:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:02:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Oct 2020 17:01:49
User entered empty.	Shetel Anassi (b) (4)	11 Sep 2020 19:09:31
	(b) (4)	



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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User accepted default value 'Pre-Dose (PREDOSE)'	Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:09:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:09:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '8 Sep 2020'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:09:31

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '12:40'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:09:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:10

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered '8 Sep 2020 12:40'	System	11 Sep 2020 19:09:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '098.3' F	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:09:31

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**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Oral (Oral)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:09:31

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:09:31



**US3862144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '082'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:09:31

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered 'bpm'	System	11 Sep 2020 19:09:31

US3862144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '016'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:09:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered 'breaths/min'	System	11 Sep 2020 19:09:31

US3862144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '119'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:09:31

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered 'mmHg'	System	11 Sep 2020 19:09:31

US3862144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '083'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:09:31

US3862144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered 'mmHg'	System	11 Sep 2020 19:09:31



US3862144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:02:10

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User closed query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight accordingly.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 15:12:28
Query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight accordingly.' answered with 'Data Corrected ' (Site from DM).	Shetel Anassi (b) (4)	20 Oct 2020 17:01:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Oct 2020 17:01:49
User opened query 'Per CDM: Subject noted as screened and dosed same day. Per CCG, 'ND' should be recorded at height and weight at Visit1 Day1. Please update ND in the field Height and Weight accordingly.' (Site from DM).	(b) (4), (b) (6)	16 Oct 2020 16:42:19
User entered empty.	Trent Davis (b) (4)	11 Sep 2020 19:09:31

US3862144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 10:02:10

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
	(b) (4)	
User entered missing code ND - Not Done; reason for change Data Entry Error	Shetel Anassi (b) (4)	20 Oct 2020 17:01:49
	(b) (4)	
User entered empty.	Trent Davis (b) (4)	11 Sep 2020 19:09:31
	(b) (4)	

US3862144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User accepted default value 'Post-Dose (POSTDOSE)'	Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:09:31

US3862144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Sep 2020 19:09:35
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 19:09:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Trent Davis (b) (4)	11 Sep 2020 19:09:35
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Sep 2020 19:09:31
User entered empty.	System	11 Sep 2020 19:09:31
	Trent Davis (b) (4)	11 Sep 2020 19:09:31
	(b) (4)	

US3862144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '8 Sep 2020'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:09:31

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '16:14'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:09:31

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered '8 Sep 2020 16:14'	System	11 Sep 2020 19:09:31

US3862144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '096.9' F	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:09:31



US3862144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Oral (Oral)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:09:31
	(b) (4)	

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:09:31

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '079'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:09:31

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered 'bpm'	System	11 Sep 2020 19:09:31

US3862144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '016'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:09:31

US3862144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered 'breaths/min'	System	11 Sep 2020 19:09:31

US3862144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '123'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:09:31

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered 'mmHg'	System	11 Sep 2020 19:09:31



US3862144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '087'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:09:31

US3862144

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered 'mmHg'	System	11 Sep 2020 19:09:31

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:02:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 20:42:31

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:02:10**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '08 Sep 2020'	(b) (4) Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 20:42:31

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 20:44:59

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 20:44:59

US3862144

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:10

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 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 20:44:59

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered 'MRNA-1273 OR PLACEBO'	System	08 Sep 2020 20:44:59



US3862144

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '08 Sep 2020'	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:44:59

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '15:37'	(b) (4) Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 20:44:59

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered '08 Sep 2020 15:37'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Left Arm (LEFT ARM)'	(b) (4) Sandra Francisco (b) (4)	08 Sep 2020 20:44:59

US3862144

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:10

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered 'ONCE'	System	08 Sep 2020 20:44:59

US3862144

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 10:02:10

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered 'INTRAMUSCULAR'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 20:46:06

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '08 Sep 2020'	(b) (4) Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 20:46:06



**US3862144**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '14:39'	(b) (4) Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 20:46:06

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered '08 Sep 2020 14:39'	System	08 Sep 2020 20:46:06

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 10:02:10**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '08 Sep 2020'	(b) (4) Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 20:46:20

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Sandra Francisco (b) (4)	08 Sep 2020 20:46:20

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 20:46:20

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:02:10**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '13:25'	(b) (4) Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 20:46:20

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered '08 Sep 2020 13:25'	System	08 Sep 2020 20:46:20

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Sandra Francisco (b) (4)	08 Sep 2020 20:46:20



**US3862144**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'No (N)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 20:46:20

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:02:10**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Sandra Francisco (b) (4) (b) (4)	08 Sep 2020 20:46:20

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered empty.	System	08 Sep 2020 20:46:20

US3862144

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 10:02:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 19:09:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Sep 2020 19:09:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Trent Davis (b) (4)	11 Sep 2020 19:09:44
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	11 Sep 2020 19:09:39
User entered empty.	Trent Davis (b) (4)	11 Sep 2020 19:09:39
	(b) (4)	

**US3862144**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered '1'	System	11 Sep 2020 19:09:44
User entered empty.	System	11 Sep 2020 19:09:39

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T15:57:44', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8cb43609-c71f-4989-8a0e-2f55c0e75e6b'	System	08 Sep 2020 20:58:38
User entered 'Yes (Y)'	System	08 Sep 2020 20:58:38

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T15:57:56', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8cb43609-c71f-4989-8a0e-2f55c0e75e6b' User entered '96.9'	System	08 Sep 2020 20:58:38



US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T15:58:22', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8cb43609-c71f-4989-8a0e-2f55c0e75e6b'	System	08 Sep 2020 20:58:38
User entered 'No (N)'	System	08 Sep 2020 20:58:38

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T15:58:33', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8cb43609-c71f-4989-8a0e-2f55c0e75e6b'	System	08 Sep 2020 20:58:38
User entered '08 Sep 2020 15:58'	System	08 Sep 2020 20:58:38

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '08 Sep 2020 15:57'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '08 Sep 2020 18:27'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T19:27:32', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '78619c8a-4175-4326-85d3-0890c79213b3'	System	09 Sep 2020 00:27:54
User entered 'Yes (Y)'	System	09 Sep 2020 00:27:54

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T19:27:40', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '78619c8a-4175-4326-85d3-0890c79213b3'	System	09 Sep 2020 00:27:54
User entered '96.4'	System	09 Sep 2020 00:27:54

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T19:27:45', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '78619c8a-4175-4326-85d3-0890c79213b3'	System	09 Sep 2020 00:27:54
User entered 'No (N)'	System	09 Sep 2020 00:27:54



**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T19:27:51', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '78619c8a-4175-4326-85d3-0890c79213b3'	System	09 Sep 2020 00:27:54
User entered '08 Sep 2020 19:27'	System	09 Sep 2020 00:27:54

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '08 Sep 2020 19:22'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 2'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-09T12:05:19', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '9daa917a-eb46-4803-b7ed-56a0f23dbc5e'	System	09 Sep 2020 17:06:25
User entered 'Yes (Y)'	System	09 Sep 2020 17:06:25

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-09T12:06:08', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '9daa917a-eb46-4803-b7ed-56a0f23dbc5e'	System	09 Sep 2020 17:06:25
User entered '98.6'	System	09 Sep 2020 17:06:25

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-09T12:06:13', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '9daa917a-eb46-4803-b7ed-56a0f23dbc5e'	System	09 Sep 2020 17:06:25
User entered 'No (N)'	System	09 Sep 2020 17:06:25

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-09T12:06:19', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '9daa917a-eb46-4803-b7ed-56a0f23dbc5e'	System	09 Sep 2020 17:06:25
User entered '09 Sep 2020 12:06'	System	09 Sep 2020 17:06:25



US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 3'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-10T12:08:03', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '0bc0c435-fa7e-4fb9-b939-d2fd7ccc3878'	System	10 Sep 2020 17:09:19
User entered 'Yes (Y)'	System	10 Sep 2020 17:09:19

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-10T12:09:01', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '0bc0c435-fa7e-4fb9-b939-d2fd7ccc3878'	System	10 Sep 2020 17:09:19
User entered '96.5'	System	10 Sep 2020 17:09:19

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-10T12:09:05', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '0bc0c435-fa7e-4fb9-b939-d2fd7ccc3878'	System	10 Sep 2020 17:09:19
User entered 'No (N)'	System	10 Sep 2020 17:09:19

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-10T12:09:13', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '0bc0c435-fa7e-4fb9-b939-d2fd7ccc3878'	System	10 Sep 2020 17:09:19
User entered '10 Sep 2020 12:09'	System	10 Sep 2020 17:09:19

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 20:44:59



**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 4'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-11T14:03:01', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '01dbffc6-ae0a-4ea6-a61e-d88a9c128819'	System	11 Sep 2020 19:04:21
User entered 'Yes (Y)'	System	11 Sep 2020 19:04:21

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-11T14:03:56', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '01dbffc6-ae0a-4ea6-a61e-d88a9c128819'	System	11 Sep 2020 19:04:21
User entered '97.9'	System	11 Sep 2020 19:04:21

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-11T14:04:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '01dbffc6-ae0a-4ea6-a61e-d88a9c128819'	System	11 Sep 2020 19:04:21
User entered 'No (N)'	System	11 Sep 2020 19:04:21

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-11T14:04:04', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '01dbffc6-ae0a-4ea6-a61e-d88a9c128819'	System	11 Sep 2020 19:04:21
User entered '11 Sep 2020 14:04'	System	11 Sep 2020 19:04:21

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 20:44:59



US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 5'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-12T12:01:05', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '0ce207be-9d67-4fe7-8eec-8c28f22a2399'	System	12 Sep 2020 17:02:00
User entered 'Yes (Y)'	System	12 Sep 2020 17:02:00

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-12T12:01:12', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '0ce207be-9d67-4fe7-8eec-8c28f22a2399'	System	12 Sep 2020 17:02:00
User entered '98.0'	System	12 Sep 2020 17:02:00

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-12T12:01:16', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '0ce207be-9d67-4fe7-8eec-8c28f22a2399'	System	12 Sep 2020 17:02:00
User entered 'No (N)'	System	12 Sep 2020 17:02:00

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-12T12:01:19', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '0ce207be-9d67-4fe7-8eec-8c28f22a2399'	System	12 Sep 2020 17:02:00
User entered '12 Sep 2020 12:01'	System	12 Sep 2020 17:02:00

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 6'	System	08 Sep 2020 20:44:59



US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-13T12:01:12', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '72473f3c-31af-4b80-b380-b4b88266b8f7'	System	13 Sep 2020 17:02:18
User entered 'Yes (Y)'	System	13 Sep 2020 17:02:18

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-13T12:01:27', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '72473f3c-31af-4b80-b380-b4b88266b8f7'	System	13 Sep 2020 17:02:18
User entered '98.0'	System	13 Sep 2020 17:02:18

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-13T12:01:30', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '72473f3c-31af-4b80-b380-b4b88266b8f7'	System	13 Sep 2020 17:02:18
User entered 'No (N)'	System	13 Sep 2020 17:02:18

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-13T12:01:32', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '72473f3c-31af-4b80-b380-b4b88266b8f7'	System	13 Sep 2020 17:02:18
User entered '13 Sep 2020 12:01'	System	13 Sep 2020 17:02:18

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 7'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-14T12:01:23', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '3109ab39-6ca8-496a-ace5-24f455998213'	System	14 Sep 2020 17:04:36
User entered 'Yes (Y)'	System	14 Sep 2020 17:04:36



US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-14T12:02:54', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '3109ab39-6ca8-496a-ace5-24f455998213' User entered '98.8'	System	14 Sep 2020 17:04:36
	System	14 Sep 2020 17:04:36

US3862144

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-14T12:02:59', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '3109ab39-6ca8-496a-ace5-24f455998213'	System	14 Sep 2020 17:04:36
User entered 'No (N)'	System	14 Sep 2020 17:04:36

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-14T12:03:04', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '3109ab39-6ca8-496a-ace5-24f455998213'	System	14 Sep 2020 17:04:36
User entered '14 Sep 2020 12:03'	System	14 Sep 2020 17:04:36

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T15:58:47', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6bb99f4c-eb0f-4e3e-807a-970f6879b8dd'	System	08 Sep 2020 20:59:20
User entered 'None (1)'	System	08 Sep 2020 20:59:20

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T15:58:58', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6bb99f4c-eb0f-4e3e-807a-970f6879b8dd'	System	08 Sep 2020 20:59:20
User entered 'No (N)'	System	08 Sep 2020 20:59:20



US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T15:59:02', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6bb99f4c-eb0f-4e3e-807a-970f6879b8dd'	System	08 Sep 2020 20:59:20
User entered 'No (N)'	System	08 Sep 2020 20:59:20

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T15:59:10', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6bb99f4c-eb0f-4e3e-807a-970f6879b8dd'	System	08 Sep 2020 20:59:20
User entered 'None (1)'	System	08 Sep 2020 20:59:20

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T15:59:15', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6bb99f4c-eb0f-4e3e-807a-970f6879b8dd'	System	08 Sep 2020 20:59:20
User entered '08 Sep 2020 15:59'	System	08 Sep 2020 20:59:20

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '08 Sep 2020 15:57'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '08 Sep 2020 18:27'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T19:27:58', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '46779e1c-49be-415f-b2e8-437f146623df'	System	09 Sep 2020 00:28:26
User entered 'None (1)'	System	09 Sep 2020 00:28:26

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T19:28:04', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '46779e1c-49be-415f-b2e8-437f146623df'	System	09 Sep 2020 00:28:26
User entered 'No (N)'	System	09 Sep 2020 00:28:26



US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T19:28:07', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '46779e1c-49be-415f-b2e8-437f146623df'	System	09 Sep 2020 00:28:26
User entered 'No (N)'	System	09 Sep 2020 00:28:26

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T19:28:19', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '46779e1c-49be-415f-b2e8-437f146623df'	System	09 Sep 2020 00:28:26
User entered 'None (1)'	System	09 Sep 2020 00:28:26

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T19:28:23', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '46779e1c-49be-415f-b2e8-437f146623df'	System	09 Sep 2020 00:28:26
User entered '08 Sep 2020 19:28'	System	09 Sep 2020 00:28:26

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '08 Sep 2020 19:22'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 2'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-09T12:06:32', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'fc038841-0874-4739-8422-41c633adc366'	System	09 Sep 2020 17:07:37
User entered 'None (1)'	System	09 Sep 2020 17:07:37

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-09T12:06:36', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'fc038841-0874-4739-8422-41c633adc366'	System	09 Sep 2020 17:07:37
User entered 'No (N)'	System	09 Sep 2020 17:07:37



US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-09T12:06:38', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'fc038841-0874-4739-8422-41c633adc366'	System	09 Sep 2020 17:07:37
User entered 'No (N)'	System	09 Sep 2020 17:07:37

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-09T12:06:41', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'fc038841-0874-4739-8422-41c633adc366'	System	09 Sep 2020 17:07:37
User entered 'None (1)'	System	09 Sep 2020 17:07:37

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-09T12:07:32', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'fc038841-0874-4739-8422-41c633adc366'	System	09 Sep 2020 17:07:37
User entered '09 Sep 2020 12:07'	System	09 Sep 2020 17:07:37

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 3'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-10T12:09:24', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '0b8f9918-1585-460f-b65c-d290aadbac92'	System	10 Sep 2020 17:12:42
User entered 'None (1)'	System	10 Sep 2020 17:12:42

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-10T12:09:30', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '0b8f9918-1585-460f-b65c-d290aeadbac92'	System	10 Sep 2020 17:12:42
User entered 'No (N)'	System	10 Sep 2020 17:12:42



US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-10T12:09:32', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '0b8f9918-1585-460f-b65c-d290aeadbac92'	System	10 Sep 2020 17:12:42
User entered 'No (N)'	System	10 Sep 2020 17:12:42

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-10T12:09:35', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '0b8f9918-1585-460f-b65c-d290aadbac92'	System	10 Sep 2020 17:12:42
User entered 'None (1)'	System	10 Sep 2020 17:12:42

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-10T12:09:38', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '0b8f9918-1585-460f-b65c-d290aeadbac92'	System	10 Sep 2020 17:12:42
User entered '10 Sep 2020 12:09'	System	10 Sep 2020 17:12:42

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 4'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-11T14:04:12', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'ee3b1362-69e6-47b1-ab2c-d41f171960e6'	System	11 Sep 2020 19:04:36
User entered 'None (1)'	System	11 Sep 2020 19:04:36

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-11T14:04:16', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'ee3b1362-69e6-47b1-ab2c-d41f171960e6'	System	11 Sep 2020 19:04:36
User entered 'No (N)'	System	11 Sep 2020 19:04:36



US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-11T14:04:20', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'ee3b1362-69e6-47b1-ab2c-d41f171960e6'	System	11 Sep 2020 19:04:36
User entered 'No (N)'	System	11 Sep 2020 19:04:36

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-11T14:04:22', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'ee3b1362-69e6-47b1-ab2c-d41f171960e6'	System	11 Sep 2020 19:04:36
User entered 'None (1)'	System	11 Sep 2020 19:04:36

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-11T14:04:27', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'ee3b1362-69e6-47b1-ab2c-d41f171960e6' User entered '11 Sep 2020 14:04'	System	11 Sep 2020 19:04:36
	System	11 Sep 2020 19:04:36

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 5'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-12T12:01:25', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '0ccb1552-d052-4ce1-9bfe-293168e9d9ad'	System	12 Sep 2020 17:02:23
User entered 'None (1)'	System	12 Sep 2020 17:02:23

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-12T12:01:28', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '0ccb1552-d052-4ce1-9bfe-293168e9d9ad'	System	12 Sep 2020 17:02:23
User entered 'No (N)'	System	12 Sep 2020 17:02:23



US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-12T12:01:30', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '0ccb1552-d052-4ce1-9bfe-293168e9d9ad'	System	12 Sep 2020 17:02:23
User entered 'No (N)'	System	12 Sep 2020 17:02:23

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-12T12:01:32', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '0ccb1552-d052-4ce1-9bfe-293168e9d9ad'	System	12 Sep 2020 17:02:23
User entered 'None (1)'	System	12 Sep 2020 17:02:23

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-12T12:01:35', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '0ccb1552-d052-4ce1-9bfe-293168e9d9ad'	System	12 Sep 2020 17:02:23
User entered '12 Sep 2020 12:01'	System	12 Sep 2020 17:02:23

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 6'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-13T12:01:38', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6de367e6-19dc-4118-a65a-9beee2e7a7a9'	System	13 Sep 2020 17:02:33
User entered 'None (1)'	System	13 Sep 2020 17:02:33

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-13T12:01:40', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6de367e6-19dc-4118-a65a-9beee2e7a7a9'	System	13 Sep 2020 17:02:33
User entered 'No (N)'	System	13 Sep 2020 17:02:33



US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-13T12:01:41', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6de367e6-19dc-4118-a65a-9beee2e7a7a9'	System	13 Sep 2020 17:02:33
User entered 'No (N)'	System	13 Sep 2020 17:02:33

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-13T12:01:44', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6de367e6-19dc-4118-a65a-9beee2e7a7a9'	System	13 Sep 2020 17:02:33
User entered 'None (1)'	System	13 Sep 2020 17:02:33

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-13T12:01:47', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6de367e6-19dc-4118-a65a-9beee2e7a7a9'	System	13 Sep 2020 17:02:33
User entered '13 Sep 2020 12:01'	System	13 Sep 2020 17:02:33

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 7'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-14T12:03:12', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '2e07e69e-5c13-4ca7-b7a5-cdf7045ddbcb'	System	14 Sep 2020 17:04:50
User entered 'None (1)'	System	14 Sep 2020 17:04:50

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-14T12:03:15', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '2e07e69e-5c13-4ca7-b7a5-cdf7045ddbeb'	System	14 Sep 2020 17:04:50
User entered 'No (N)'	System	14 Sep 2020 17:04:50



US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-14T12:03:18', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '2e07e69e-5c13-4ca7-b7a5-cdf7045ddbcb'	System	14 Sep 2020 17:04:50
User entered 'No (N)'	System	14 Sep 2020 17:04:50

US3862144

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-14T12:03:21', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '2e07e69e-5c13-4ca7-b7a5-cdf7045ddbcb'	System	14 Sep 2020 17:04:50
User entered 'None (1)'	System	14 Sep 2020 17:04:50

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-14T12:03:24', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '2e07e69e-5c13-4ca7-b7a5-cdf7045ddbeb'	System	14 Sep 2020 17:04:50
User entered '14 Sep 2020 12:03'	System	14 Sep 2020 17:04:50

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T15:59:21', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '9f7d2140-3bc2-4b4f-aa7f-c514d13f8d72'	System	08 Sep 2020 20:59:54
User entered 'None (0)'	System	08 Sep 2020 20:59:54

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T15:59:24', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '9f7d2140-3bc2-4b4f-aa7f-c514d13f8d72'	System	08 Sep 2020 20:59:54
User entered 'None (0)'	System	08 Sep 2020 20:59:54



US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T15:59:27', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '9f7d2140-3bc2-4b4f-aa7f-c514d13f8d72'	System	08 Sep 2020 20:59:54
User entered 'None (0)'	System	08 Sep 2020 20:59:54

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T15:59:30', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '9f7d2140-3bc2-4b4f-aa7f-c514d13f8d72'	System	08 Sep 2020 20:59:54
User entered 'None (0)'	System	08 Sep 2020 20:59:54

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T15:59:33', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '9f7d2140-3bc2-4b4f-aa7f-c514d13f8d72'	System	08 Sep 2020 20:59:54
User entered 'None (0)'	System	08 Sep 2020 20:59:54

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T15:59:36', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '9f7d2140-3bc2-4b4f-aa7f-c514d13f8d72'	System	08 Sep 2020 20:59:54
User entered 'None (0)'	System	08 Sep 2020 20:59:54

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T15:59:45', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '9f7d2140-3bc2-4b4f-aa7f-c514d13f8d72'	System	08 Sep 2020 20:59:54
User entered 'No (N)'	System	08 Sep 2020 20:59:54

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T15:59:49', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '9f7d2140-3bc2-4b4f-aa7f-c514d13f8d72'	System	08 Sep 2020 20:59:54
User entered '08 Sep 2020 15:59'	System	08 Sep 2020 20:59:54

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '08 Sep 2020 15:57'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '08 Sep 2020 18:27'	System	08 Sep 2020 20:44:59



US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 1, after vaccination (at home)'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T19:28:27', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8a8c8a5f-3290-421c-b68b-95b61fe3303e'	System	09 Sep 2020 00:28:53
User entered 'None (0)'	System	09 Sep 2020 00:28:53

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T19:28:31', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8a8c8a5f-3290-421c-b68b-95b61fe3303e'	System	09 Sep 2020 00:28:53
User entered 'None (0)'	System	09 Sep 2020 00:28:53

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T19:28:34', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8a8c8a5f-3290-421c-b68b-95b61fe3303e'	System	09 Sep 2020 00:28:53
User entered 'None (0)'	System	09 Sep 2020 00:28:53

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T19:28:37', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8a8c8a5f-3290-421c-b68b-95b61fe3303e'	System	09 Sep 2020 00:28:53
User entered 'None (0)'	System	09 Sep 2020 00:28:53

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T19:28:40', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8a8c8a5f-3290-421c-b68b-95b61fe3303e'	System	09 Sep 2020 00:28:53
User entered 'None (0)'	System	09 Sep 2020 00:28:53

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T19:28:43', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8a8c8a5f-3290-421c-b68b-95b61fe3303e'	System	09 Sep 2020 00:28:53
User entered 'None (0)'	System	09 Sep 2020 00:28:53

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T19:28:46', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8a8c8a5f-3290-421c-b68b-95b61fe3303e'	System	09 Sep 2020 00:28:53
User entered 'No (N)'	System	09 Sep 2020 00:28:53



**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-08T19:28:50', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8a8c8a5f-3290-421c-b68b-95b61fe3303e'	System	09 Sep 2020 00:28:53
User entered '08 Sep 2020 19:28'	System	09 Sep 2020 00:28:53

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '08 Sep 2020 19:22'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '09 Sep 2020 11:59'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 2'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-09T12:07:49', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '60e888b9-b3ad-4c05-a8e9-3ab20d4c4d03'	System	09 Sep 2020 17:08:13
User entered 'None (0)'	System	09 Sep 2020 17:08:13

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-09T12:07:51', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '60e888b9-b3ad-4c05-a8e9-3ab20d4c4d03'	System	09 Sep 2020 17:08:13
User entered 'None (0)'	System	09 Sep 2020 17:08:13

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-09T12:07:53', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '60e888b9-b3ad-4c05-a8e9-3ab20d4c4d03'	System	09 Sep 2020 17:08:13
User entered 'None (0)'	System	09 Sep 2020 17:08:13

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-09T12:07:56', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '60e888b9-b3ad-4c05-a8e9-3ab20d4c4d03'	System	09 Sep 2020 17:08:13
User entered 'None (0)'	System	09 Sep 2020 17:08:13



US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-09T12:08:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '60e888b9-b3ad-4c05-a8e9-3ab20d4c4d03'	System	09 Sep 2020 17:08:13
User entered 'None (0)'	System	09 Sep 2020 17:08:13

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-09T12:08:02', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '60e888b9-b3ad-4c05-a8e9-3ab20d4c4d03'	System	09 Sep 2020 17:08:13
User entered 'None (0)'	System	09 Sep 2020 17:08:13

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-09T12:08:05', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '60e888b9-b3ad-4c05-a8e9-3ab20d4c4d03'	System	09 Sep 2020 17:08:13
User entered 'No (N)'	System	09 Sep 2020 17:08:13

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-09T12:08:10', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '60e888b9-b3ad-4c05-a8e9-3ab20d4c4d03'	System	09 Sep 2020 17:08:13
User entered '09 Sep 2020 12:08'	System	09 Sep 2020 17:08:13

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '09 Sep 2020 12:00'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '10 Sep 2020 11:59'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 3'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-10T12:09:42', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6a38c969-a1c6-4dbb-b562-f384f00dc2bd'	System	10 Sep 2020 17:12:48
User entered 'None (0)'	System	10 Sep 2020 17:12:48



**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-10T12:09:45', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6a38c969-a1c6-4dbb-b562-f384f00dc2bd'	System	10 Sep 2020 17:12:48
User entered 'None (0)'	System	10 Sep 2020 17:12:48

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-10T12:09:48', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6a38c969-a1c6-4dbb-b562-f384f00dc2bd'	System	10 Sep 2020 17:12:48
User entered 'None (0)'	System	10 Sep 2020 17:12:48

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-10T12:09:51', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6a38c969-a1c6-4dbb-b562-f384f00dc2bd'	System	10 Sep 2020 17:12:48
User entered 'None (0)'	System	10 Sep 2020 17:12:48

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-10T12:09:55', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6a38c969-a1c6-4dbb-b562-f384f00dc2bd'	System	10 Sep 2020 17:12:48
User entered 'None (0)'	System	10 Sep 2020 17:12:48

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-10T12:09:59', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6a38c969-a1c6-4dbb-b562-f384f00dc2bd'	System	10 Sep 2020 17:12:48
User entered 'None (0)'	System	10 Sep 2020 17:12:48

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-10T12:10:03', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6a38c969-a1c6-4dbb-b562-f384f00dc2bd'	System	10 Sep 2020 17:12:48
User entered 'No (N)'	System	10 Sep 2020 17:12:48

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-10T12:10:06', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6a38c969-a1c6-4dbb-b562-f384f00dc2bd'	System	10 Sep 2020 17:12:48
User entered '10 Sep 2020 12:10'	System	10 Sep 2020 17:12:48

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '10 Sep 2020 12:00'	System	08 Sep 2020 20:44:59



**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '11 Sep 2020 11:59'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 4'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-11T14:04:32', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '96ff760e-a60d-4088-baf6-0fedf2a1d3a0'	System	11 Sep 2020 19:04:53
User entered 'None (0)'	System	11 Sep 2020 19:04:53

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-11T14:04:33', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '96ff760e-a60d-4088-baf6-0fedf2a1d3a0'	System	11 Sep 2020 19:04:53
User entered 'None (0)'	System	11 Sep 2020 19:04:53

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-11T14:04:35', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '96ff760e-a60d-4088-baf6-0fedf2a1d3a0'	System	11 Sep 2020 19:04:53
User entered 'None (0)'	System	11 Sep 2020 19:04:53

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-11T14:04:37', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '96ff760e-a60d-4088-baf6-0fedf2a1d3a0'	System	11 Sep 2020 19:04:53
User entered 'None (0)'	System	11 Sep 2020 19:04:53

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-11T14:04:39', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '96ff760e-a60d-4088-baf6-0fedf2a1d3a0'	System	11 Sep 2020 19:04:53
User entered 'None (0)'	System	11 Sep 2020 19:04:53

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-11T14:04:41', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '96ff760e-a60d-4088-baf6-0fedf2a1d3a0'	System	11 Sep 2020 19:04:53
User entered 'None (0)'	System	11 Sep 2020 19:04:53



US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-11T14:04:46', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '96ff760e-a60d-4088-baf6-0fedf2a1d3a0'	System	11 Sep 2020 19:04:53
User entered 'No (N)'	System	11 Sep 2020 19:04:53

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-11T14:04:49', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '96ff760e-a60d-4088-baf6-0fedf2a1d3a0'	System	11 Sep 2020 19:04:53
User entered '11 Sep 2020 14:04'	System	11 Sep 2020 19:04:53

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '11 Sep 2020 12:00'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '12 Sep 2020 11:59'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 5'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-12T12:01:42', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '4fce78c6-ed0c-4e42-9fc0-783dc5c0cd36'	System	12 Sep 2020 17:02:52
User entered 'None (0)'	System	12 Sep 2020 17:02:52

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-12T12:01:44', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '4fce78c6-ed0c-4e42-9fc0-783dc5c0cd36'	System	12 Sep 2020 17:02:52
User entered 'None (0)'	System	12 Sep 2020 17:02:52

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-12T12:01:46', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '4fce78c6-ed0c-4e42-9fc0-783dc5c0cd36'	System	12 Sep 2020 17:02:52
User entered 'None (0)'	System	12 Sep 2020 17:02:52



US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-12T12:01:48', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '4fce78c6-ed0c-4e42-9fc0-783dc5c0cd36'	System	12 Sep 2020 17:02:52
User entered 'None (0)'	System	12 Sep 2020 17:02:52

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-12T12:01:49', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '4fce78c6-ed0c-4e42-9fc0-783dc5c0cd36'	System	12 Sep 2020 17:02:52
User entered 'None (0)'	System	12 Sep 2020 17:02:52

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-12T12:01:52', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '4fce78c6-ed0c-4e42-9fc0-783dc5c0cd36'	System	12 Sep 2020 17:02:52
User entered 'None (0)'	System	12 Sep 2020 17:02:52

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-12T12:01:57', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '4fce78c6-ed0c-4e42-9fc0-783dc5c0cd36'	System	12 Sep 2020 17:02:52
User entered 'No (N)'	System	12 Sep 2020 17:02:52

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-12T12:02:01', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '4fce78c6-ed0c-4e42-9fc0-783dc5c0cd36'	System	12 Sep 2020 17:02:52
User entered '12 Sep 2020 12:02'	System	12 Sep 2020 17:02:52

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '12 Sep 2020 12:00'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '13 Sep 2020 11:59'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 6'	System	08 Sep 2020 20:44:59



US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-13T12:01:51', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'febf3310-caf9-4644-b1be-ab3e4d8daba8'	System	13 Sep 2020 17:02:55
User entered 'None (0)'	System	13 Sep 2020 17:02:55

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-13T12:01:54', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'febf3310-caf9-4644-b1be-ab3e4d8daba8'	System	13 Sep 2020 17:02:55
User entered 'None (0)'	System	13 Sep 2020 17:02:55

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-13T12:01:57', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'febf3310-caf9-4644-b1be-ab3e4d8daba8'	System	13 Sep 2020 17:02:55
User entered 'None (0)'	System	13 Sep 2020 17:02:55

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-13T12:01:59', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'febf3310-caf9-4644-b1be-ab3e4d8daba8'	System	13 Sep 2020 17:02:55
User entered 'None (0)'	System	13 Sep 2020 17:02:55

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-13T12:02:03', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'febf3310-caf9-4644-b1be-ab3e4d8daba8'	System	13 Sep 2020 17:02:55
User entered 'None (0)'	System	13 Sep 2020 17:02:55

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-13T12:02:05', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'febf3310-caf9-4644-b1be-ab3e4d8daba8'	System	13 Sep 2020 17:02:55
User entered 'None (0)'	System	13 Sep 2020 17:02:55

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-13T12:02:08', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'febf3310-caf9-4644-b1be-ab3e4d8daba8'	System	13 Sep 2020 17:02:55
User entered 'No (N)'	System	13 Sep 2020 17:02:55

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-13T12:02:12', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'febf3310-caf9-4644-b1be-ab3e4d8daba8'	System	13 Sep 2020 17:02:55
User entered '13 Sep 2020 12:02'	System	13 Sep 2020 17:02:55



**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '13 Sep 2020 12:00'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '14 Sep 2020 11:59'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 7'	System	08 Sep 2020 20:44:59

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-14T12:03:31', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '24cad436-f789-4363-92f5-18dbe619e13b'	System	14 Sep 2020 17:05:14
User entered 'None (0)'	System	14 Sep 2020 17:05:14

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-14T12:03:33', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '24cad436-f789-4363-92f5-18dbe619e13b'	System	14 Sep 2020 17:05:14
User entered 'None (0)'	System	14 Sep 2020 17:05:14

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-14T12:03:35', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '24cad436-f789-4363-92f5-18dbe619e13b'	System	14 Sep 2020 17:05:14
User entered 'None (0)'	System	14 Sep 2020 17:05:14

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-14T12:03:38', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '24cad436-f789-4363-92f5-18dbe619e13b'	System	14 Sep 2020 17:05:14
User entered 'None (0)'	System	14 Sep 2020 17:05:14

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-14T12:03:41', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '24cad436-f789-4363-92f5-18dbe619e13b'	System	14 Sep 2020 17:05:14
User entered 'None (0)'	System	14 Sep 2020 17:05:14



US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-14T12:03:43', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '24cad436-f789-4363-92f5-18dbe619e13b'	System	14 Sep 2020 17:05:14
User entered 'None (0)'	System	14 Sep 2020 17:05:14

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-14T12:03:47', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '24cad436-f789-4363-92f5-18dbe619e13b'	System	14 Sep 2020 17:05:14
User entered 'No (N)'	System	14 Sep 2020 17:05:14

US3862144

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-09-14T12:03:56', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '24cad436-f789-4363-92f5-18dbe619e13b'	System	14 Sep 2020 17:05:14
User entered '14 Sep 2020 12:03'	System	14 Sep 2020 17:05:14

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '14 Sep 2020 12:00'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '15 Sep 2020 11:59'	System	08 Sep 2020 20:44:59

**US3862144**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	15 Sep 2020 22:17:33

**US3862144**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '15 Sep 2020'	(b) (4) Sandra Francisco (b) (4)	15 Sep 2020 22:17:33

**US3862144**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	15 Sep 2020 22:17:33



**US3862144**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Sandra Francisco (b) (4) (b) (4)	15 Sep 2020 22:17:33

US3862144

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 10:02:10

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Sep 2020 23:43:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 23:43:33
User entered 'Yes (Y)' reason for change: Per Query Resolution	Chanei Henry (b) (4)	16 Sep 2020 23:43:33
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Sep 2020 22:22:39
User entered empty.	Sandra Francisco (b) (4)	15 Sep 2020 22:22:39
	(b) (4)	

**US3862144**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered '1'	System	16 Sep 2020 23:43:33
User entered empty.	System	15 Sep 2020 22:22:39

**US3862144**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	22 Sep 2020 19:50:34
	(b) (4)	

**US3862144**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '22 Sep 2020'	(b) (4) Thea Marie Cordero	22 Sep 2020 19:50:34
	(b) (4)	

**US3862144**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Thea Marie Cordero (b) (4)	22 Sep 2020 19:50:34

**US3862144**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Thea Marie Cordero	22 Sep 2020 19:50:34
	(b) (4)	

**US3862144**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	22 Sep 2020 19:50:40
	(b) (4)	



**US3862144**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered 'I'	System	22 Sep 2020 19:50:40

**US3862144**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Sandra Francisco (b) (4)	30 Sep 2020 20:59:50

**US3862144**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '30 Sep 2020'	(b) (4) Sandra Francisco (b) (4)	30 Sep 2020 20:59:50

**US3862144**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	30 Sep 2020 20:59:50

**US3862144**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Sandra Francisco (b) (4) (b) (4)	30 Sep 2020 20:59:50

**US3862144**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4) (b) (4)	07 Oct 2020 15:08:59

**US3862144**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered 'I'	System	07 Oct 2020 15:08:59

US3862144

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 10:02:10

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	07 Oct 2020 15:11:00



**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '7 Oct 2020'	(b) (4) Trent Davis (b) (4)	07 Oct 2020 15:11:00

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[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 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Clinic (Clinic)'	(b) (4) Trent Davis (b) (4) (b) (4)	07 Oct 2020 15:11:00

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered 'VISIT2'	System	07 Oct 2020 15:11:00

US3862144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:10

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User accepted default value 'Pre-Dose (PREDOSE)'	Trent Davis (b) (4) (b) (4)	07 Oct 2020 15:12:28

US3862144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4) (b) (4)	07 Oct 2020 15:12:28

US3862144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '7 Oct 2020'	(b) (4) Trent Davis (b) (4)	07 Oct 2020 15:12:28

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '09:00'	(b) (4) Trent Davis (b) (4) (b) (4)	07 Oct 2020 15:12:28

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered '7 Oct 2020 09:00'	System	07 Oct 2020 15:12:28



US3862144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '097.9' F	(b) (4) Trent Davis (b) (4) (b) (4)	07 Oct 2020 15:12:28

US3862144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 15:12:42
Query 'Data is required. Please provide.' answered by System data change (Site from System).		07 Oct 2020 15:12:42
User closed query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	System	07 Oct 2020 15:12:42
User entered 'Other (Other)' reason for change: Data Entry Error	Trent Davis (b) (4)	07 Oct 2020 15:12:42
	(b) (4)	
User opened query 'Route of measurement is not Other, however, specify is provided. Please correct.' (Site from System).	System	07 Oct 2020 15:12:28
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 15:12:28
User entered empty.	Trent Davis (b) (4)	07 Oct 2020 15:12:28
	(b) (4)	

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'temporal'	(b) (4) Trent Davis (b) (4) (b) (4)	07 Oct 2020 15:12:28

US3862144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '078'	(b) (4) Trent Davis (b) (4) (b) (4)	07 Oct 2020 15:12:28

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered 'bpm'	System	07 Oct 2020 15:12:28

US3862144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '016'	(b) (4) Trent Davis (b) (4)	07 Oct 2020 15:12:28

US3862144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered 'breaths/min'	System	07 Oct 2020 15:12:28

US3862144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:10

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '127'	(b) (4) Trent Davis (b) (4) (b) (4)	07 Oct 2020 15:12:28



US3862144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered 'mmHg'	System	07 Oct 2020 15:12:28

US3862144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '091'	(b) (4) Trent Davis (b) (4) (b) (4)	07 Oct 2020 15:12:28

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered 'mmHg'	System	07 Oct 2020 15:12:28

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User accepted default value 'Post-Dose (POSTDOSE)'	Trent Davis (b) (4) (b) (4)	07 Oct 2020 15:12:28

US3862144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4) (b) (4)	07 Oct 2020 15:12:28

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '7 Oct 2020'	(b) (4) Trent Davis (b) (4)	07 Oct 2020 15:12:28

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Oct 2020 22:56:31
Query 'Data is required. Please provide.' answered by System	System	13 Oct 2020 22:56:31
data change (Site from System).		
User entered '10:25' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Oct 2020 22:56:31
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Oct 2020 15:12:28
User entered empty.	Trent Davis (b) (4)	07 Oct 2020 15:12:28
	(b) (4)	

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered '7 Oct 2020 10:25'	System	13 Oct 2020 22:56:31
User entered empty.	System	07 Oct 2020 15:12:28



US3862144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Oct 2020 22:56:31
Query 'Data is required. Please provide.' answered by System	System	13 Oct 2020 22:56:31
data change (Site from System).		13 Oct 2020 22:56:31
User entered '97.5' F reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Oct 2020 22:56:31
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Oct 2020 15:12:28
User entered empty.	Trent Davis (b) (4)	07 Oct 2020 15:12:28
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Other (Other)' reason for change: Data Entry Error	(b) (4)	13 Oct 2020 22:56:31
User entered empty.	Carrie Kibler (b) (4)	07 Oct 2020 15:12:28
	(b) (4)	

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**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'temporal' reason for change: Data Entry Error	(b) (4)	13 Oct 2020 22:56:31
User entered empty.	Carrie Kibler (b) (4)	13 Oct 2020 22:56:31
	(b) (4)	
	Trent Davis (b) (4)	07 Oct 2020 15:12:28
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Oct 2020 22:56:31
Query 'Data is required. Please provide.' answered by System	System	13 Oct 2020 22:56:31
data change (Site from System).		13 Oct 2020 22:56:31
User entered '80' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Oct 2020 22:56:31
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Oct 2020 15:12:28
User entered empty.	Trent Davis (b) (4)	07 Oct 2020 15:12:28
	(b) (4)	

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**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered 'bpm'	System	13 Oct 2020 22:56:31
User entered empty.	System	07 Oct 2020 15:12:28

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Oct 2020 22:56:31
Query 'Data is required. Please provide.' answered by System	System	13 Oct 2020 22:56:31
data change (Site from System).		13 Oct 2020 22:56:31
User entered '16' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Oct 2020 22:56:31
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	07 Oct 2020 15:12:28
User entered empty.	Trent Davis (b) (4)	07 Oct 2020 15:12:28
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered 'breaths/min'	System	13 Oct 2020 22:56:31
User entered empty.	System	07 Oct 2020 15:12:28

US3862144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Oct 2020 22:56:31
Query 'Data is required. Please provide.' answered by System	System	13 Oct 2020 22:56:31
data change (Site from System).		13 Oct 2020 22:56:31
User entered '117' reason for change: Data Entry	Carrie Kibler (b) (4)	13 Oct 2020 22:56:31
Error	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 15:12:28
User entered empty.	Trent Davis (b) (4)	07 Oct 2020 15:12:28
	(b) (4)	



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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered 'mmHg'	System	13 Oct 2020 22:56:31
User entered empty.	System	07 Oct 2020 15:12:28

US3862144

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	13 Oct 2020 22:56:31
Query 'Data is required. Please provide.' answered by System	System	13 Oct 2020 22:56:31
data change (Site from System).		
User entered '88' reason for change: Data Entry Error	Carrie Kibler (b) (4)	13 Oct 2020 22:56:31
	(b) (4)	
User opened query 'Data is required. Please provide.' (Site from System).	System	07 Oct 2020 15:12:28
User entered empty.	Trent Davis (b) (4)	07 Oct 2020 15:12:28
	(b) (4)	

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered 'mmHg'	System	13 Oct 2020 22:56:31
User entered empty.	System	07 Oct 2020 15:12:28

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:02:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	07 Oct 2020 15:12:54

US3862144

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '7 Oct 2020'	(b) (4) Trent Davis (b) (4)	07 Oct 2020 15:12:54

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Yes (Y)'	(b) (4) Chanei Henry (b) (4)	07 Oct 2020 15:11:53

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered empty.	(b) (4) Chanei Henry (b) (4)	07 Oct 2020 15:11:53

US3862144

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:10

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 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered empty.	(b) (4) Chanei Henry (b) (4)	07 Oct 2020 15:11:53
	(b) (4)	



**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered 'MRNA-1273 OR PLACEBO'	System	07 Oct 2020 15:11:53

US3862144

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '7 Oct 2020'	(b) (4) Chanei Henry (b) (4)	07 Oct 2020 15:11:53
	(b) (4)	

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '09:53'	(b) (4) Chanei Henry (b) (4)	07 Oct 2020 15:11:53

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered '7 Oct 2020 09:53'	System	07 Oct 2020 15:11:53

US3862144

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:10

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Left Arm (LEFT ARM)'	(b) (4) Chanei Henry (b) (4)	07 Oct 2020 15:11:53

US3862144

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:10

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered 'ONCE'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered 'INTRAMUSCULAR'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	07 Oct 2020 15:14:58



**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '7 Oct 2020'	(b) (4) Trent Davis (b) (4) (b) (4)	07 Oct 2020 15:14:58

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '09:20'	(b) (4) Trent Davis (b) (4) (b) (4)	07 Oct 2020 15:14:58

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered '7 Oct 2020 09:20'	System	07 Oct 2020 15:14:58

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 10:02:10**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '7 Oct 2020'	(b) (4) Trent Davis (b) (4)	07 Oct 2020 15:15:14

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Trent Davis (b) (4) (b) (4)	07 Oct 2020 15:15:14

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	07 Oct 2020 15:15:14

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered empty.	(b) (4) Trent Davis (b) (4)	07 Oct 2020 15:15:14

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered empty.	System	07 Oct 2020 15:15:14



**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Trent Davis (b) (4) (b) (4)	07 Oct 2020 15:15:14

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4) (b) (4)	07 Oct 2020 15:15:14

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:02:10**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '09:14'	(b) (4) Trent Davis (b) (4) (b) (4)	07 Oct 2020 15:15:14

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered '7 Oct 2020 09:14'	System	07 Oct 2020 15:15:14

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	13 Oct 2020 22:56:39

**US3862144**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered 'I'	System	13 Oct 2020 22:56:39

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T10:24:57', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '999feb3e-e4d6-4efb-b226-b2406fe00ec3'	System	07 Oct 2020 15:25:22
User entered 'Yes (Y)'	System	07 Oct 2020 15:25:22



US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T10:25:03', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '999feb3e-e4d6-4efb-b226-b2406fe00ec3'	System	07 Oct 2020 15:25:22
User entered '97.5'	System	07 Oct 2020 15:25:22

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T10:25:12', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '999feb3e-e4d6-4efb-b226-b2406fe00ec3'	System	07 Oct 2020 15:25:22
User entered 'No (N)'	System	07 Oct 2020 15:25:22

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T10:25:18', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '999feb3e-e4d6-4efb-b226-b2406fe00ec3'	System	07 Oct 2020 15:25:22
User entered '07 Oct 2020 10:25'	System	07 Oct 2020 15:25:22

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '07 Oct 2020 10:13'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '07 Oct 2020 12:43'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T13:40:02', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd8a58135-d8bb-4d1f-b713-8450d1986a9b'	System	07 Oct 2020 18:40:37
User entered 'Yes (Y)'	System	07 Oct 2020 18:40:37

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T13:40:22', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd8a58135-d8bb-4d1f-b713-8450d1986a9b'	System	07 Oct 2020 18:40:37
User entered '97.7'	System	07 Oct 2020 18:40:37



US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T13:40:27', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd8a58135-d8bb-4d1f-b713-8450d1986a9b'	System	07 Oct 2020 18:40:37
User entered 'No (N)'	System	07 Oct 2020 18:40:37

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T13:40:31', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd8a58135-d8bb-4d1f-b713-8450d1986a9b'	System	07 Oct 2020 18:40:37
User entered '07 Oct 2020 13:40'	System	07 Oct 2020 18:40:37

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '07 Oct 2020 13:38'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 2'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-08T12:01:55', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'da5817af-bbb2-42d2-a83a-51e2962943a7'	System	08 Oct 2020 17:03:03
User entered 'Yes (Y)'	System	08 Oct 2020 17:03:03

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-08T12:02:11', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'da5817af-bbb2-42d2-a83a-51e2962943a7' User entered '96.1'	System	08 Oct 2020 17:03:03
	System	08 Oct 2020 17:03:03

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-08T12:02:17', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'da5817af-bbb2-42d2-a83a-51e2962943a7'	System	08 Oct 2020 17:03:03
User entered 'No (N)'	System	08 Oct 2020 17:03:03



US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:10

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-08T12:02:19', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'da5817af-bbb2-42d2-a83a-51e2962943a7'	System	08 Oct 2020 17:03:03
User entered '08 Oct 2020 12:02'	System	08 Oct 2020 17:03:03

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 10:02:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 3'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-09T12:01:25', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'e432411c-403e-44ed-b7db-59259a041213'	System	09 Oct 2020 17:02:19
User entered 'Yes (Y)'	System	09 Oct 2020 17:02:19

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-09T12:02:04', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'e432411c-403e-44ed-b7db-59259a041213' User entered '97.5'	System	09 Oct 2020 17:02:19
	System	09 Oct 2020 17:02:19

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-09T12:02:07', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'e432411c-403e-44ed-b7db-59259a041213'	System	09 Oct 2020 17:02:19
User entered 'No (N)'	System	09 Oct 2020 17:02:19

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-09T12:02:10', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'e432411c-403e-44ed-b7db-59259a041213'	System	09 Oct 2020 17:02:19
User entered '09 Oct 2020 12:02'	System	09 Oct 2020 17:02:19



**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 4'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-10T13:21:25', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '1154b2fb-6132-4c58-b7c5-e772a9b22856'	System	10 Oct 2020 18:21:47
User entered 'Yes (Y)'	System	10 Oct 2020 18:21:47

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-10T13:21:34', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '1154b2fb-6132-4c58-b7c5-e772a9b22856'	System	10 Oct 2020 18:21:47
User entered '97.8'	System	10 Oct 2020 18:21:47

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-10T13:21:37', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '1154b2fb-6132-4c58-b7c5-e772a9b22856'	System	10 Oct 2020 18:21:47
User entered 'No (N)'	System	10 Oct 2020 18:21:47

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-10T13:21:42', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '1154b2fb-6132-4c58-b7c5-e772a9b22856'	System	10 Oct 2020 18:21:47
User entered '10 Oct 2020 13:21'	System	10 Oct 2020 18:21:47

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 15:11:53



US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 10:02:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 5'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-11T12:28:21', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '00d939d6-1a31-4769-9a65-a4f2a014f662'	System	11 Oct 2020 17:28:37
User entered 'Yes (Y)'	System	11 Oct 2020 17:28:37

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-11T12:28:25', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '00d939d6-1a31-4769-9a65-a4f2a014f662'	System	11 Oct 2020 17:28:37
User entered '97.7'	System	11 Oct 2020 17:28:37

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-11T12:28:29', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '00d939d6-1a31-4769-9a65-a4f2a014f662'	System	11 Oct 2020 17:28:37
User entered 'No (N)'	System	11 Oct 2020 17:28:37

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-11T12:28:32', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '00d939d6-1a31-4769-9a65-a4f2a014f662'	System	11 Oct 2020 17:28:37
User entered '11 Oct 2020 12:28'	System	11 Oct 2020 17:28:37

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 15:11:53



US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 6'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:10

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 15:11:53



US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 10:02:10

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 7'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:10

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:10

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 10:02:10

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50



**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T10:25:27', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8022d558-0fca-4f43-ac6a-46630deb8a9b'	System	07 Oct 2020 15:25:59
User entered 'None (1)'	System	07 Oct 2020 15:25:59

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T10:25:33', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8022d558-0fca-4f43-ac6a-46630deb8a9b'	System	07 Oct 2020 15:25:59
User entered 'No (N)'	System	07 Oct 2020 15:25:59

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T10:25:44', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8022d558-0fca-4f43-ac6a-46630deb8a9b'	System	07 Oct 2020 15:25:59
User entered 'No (N)'	System	07 Oct 2020 15:25:59

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T10:25:50', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8022d558-0fca-4f43-ac6a-46630deb8a9b'	System	07 Oct 2020 15:25:59
User entered 'None (1)'	System	07 Oct 2020 15:25:59

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T10:25:54', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8022d558-0fca-4f43-ac6a-46630deb8a9b'	System	07 Oct 2020 15:25:59
User entered '07 Oct 2020 10:25'	System	07 Oct 2020 15:25:59



**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '07 Oct 2020 10:13'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '07 Oct 2020 12:43'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T13:40:37', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '38deadab-6487-426d-b0bf-98b3d1fb8075'	System	07 Oct 2020 18:41:02
User entered 'None (1)'	System	07 Oct 2020 18:41:02

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T13:40:41', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '38deadab-6487-426d-b0bf-98b3d1fb8075'	System	07 Oct 2020 18:41:02
User entered 'No (N)'	System	07 Oct 2020 18:41:02

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T13:40:48', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '38deadab-6487-426d-b0bf-98b3d1fb8075'	System	07 Oct 2020 18:41:02
User entered 'No (N)'	System	07 Oct 2020 18:41:02

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T13:40:50', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '38deadab-6487-426d-b0bf-98b3d1fb8075'	System	07 Oct 2020 18:41:02
User entered 'None (1)'	System	07 Oct 2020 18:41:02

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T13:40:53', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '38deadab-6487-426d-b0bf-98b3d1fb8075'	System	07 Oct 2020 18:41:02
User entered '07 Oct 2020 13:40'	System	07 Oct 2020 18:41:02



**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '07 Oct 2020 13:38'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 2'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-08T12:02:26', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'b442c3c3-190c-4f10-aaee-a7abd6c9f87f'	System	08 Oct 2020 17:03:17
User entered 'None (1)'	System	08 Oct 2020 17:03:17

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-08T12:02:28', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'b442c3c3-190c-4f10-aaee-a7abd6c9f87f'	System	08 Oct 2020 17:03:17
User entered 'No (N)'	System	08 Oct 2020 17:03:17

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-08T12:02:31', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'b442c3c3-190c-4f10-aaee-a7abd6c9f87f'	System	08 Oct 2020 17:03:17
User entered 'No (N)'	System	08 Oct 2020 17:03:17

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-08T12:02:33', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'b442c3c3-190c-4f10-aaee-a7abd6c9f87f'	System	08 Oct 2020 17:03:17
User entered 'None (1)'	System	08 Oct 2020 17:03:17

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-08T12:02:36', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'b442c3c3-190c-4f10-aaee-a7abd6c9f87f' User entered '08 Oct 2020 12:02'	System	08 Oct 2020 17:03:17
	System	08 Oct 2020 17:03:17



**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 3'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-09T12:02:20', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8bc252d4-b1a4-466f-8e18-a312cac5b23a'	System	09 Oct 2020 17:03:06
User entered 'None (1)'	System	09 Oct 2020 17:03:06

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-09T12:02:33', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8bc252d4-b1a4-466f-8e18-a312cac5b23a'	System	09 Oct 2020 17:03:06
User entered 'No (N)'	System	09 Oct 2020 17:03:06

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-09T12:02:49', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8bc252d4-b1a4-466f-8e18-a312cac5b23a'	System	09 Oct 2020 17:03:06
User entered 'No (N)'	System	09 Oct 2020 17:03:06

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-09T12:02:57', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8bc252d4-b1a4-466f-8e18-a312cac5b23a'	System	09 Oct 2020 17:03:06
User entered 'None (1)'	System	09 Oct 2020 17:03:06

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-09T12:03:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8bc252d4-b1a4-466f-8e18-a312cac5b23a'	System	09 Oct 2020 17:03:06
User entered '09 Oct 2020 12:03'	System	09 Oct 2020 17:03:06



**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:10

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 4'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-10T13:22:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '3febcef8-b67a-49f5-9746-0902880f0891'	System	10 Oct 2020 18:22:38
User entered 'None (1)'	System	10 Oct 2020 18:22:38

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-10T13:22:10', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '3febcef8-b67a-49f5-9746-0902880f0891'	System	10 Oct 2020 18:22:38
User entered 'No (N)'	System	10 Oct 2020 18:22:38

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-10T13:22:12', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '3febcef8-b67a-49f5-9746-0902880f0891'	System	10 Oct 2020 18:22:38
User entered 'No (N)'	System	10 Oct 2020 18:22:38

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-10T13:22:15', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '3febcef8-b67a-49f5-9746-0902880f0891'	System	10 Oct 2020 18:22:38
User entered 'None (1)'	System	10 Oct 2020 18:22:38

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-10T13:22:32', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '3febcef8-b67a-49f5-9746-0902880f0891'	System	10 Oct 2020 18:22:38
User entered '10 Oct 2020 13:22'	System	10 Oct 2020 18:22:38



**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 5'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-11T12:28:38', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'bb13f024-0648-46ad-ac77-777f3cfb069a'	System	11 Oct 2020 17:28:53
User entered 'None (1)'	System	11 Oct 2020 17:28:53

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-11T12:28:42', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'bb13f024-0648-46ad-ac77-777f3cfb069a'	System	11 Oct 2020 17:28:53
User entered 'No (N)'	System	11 Oct 2020 17:28:53

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-11T12:28:44', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'bb13f024-0648-46ad-ac77-777f3cfb069a'	System	11 Oct 2020 17:28:53
User entered 'No (N)'	System	11 Oct 2020 17:28:53

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-11T12:28:46', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'bb13f024-0648-46ad-ac77-777f3cfb069a'	System	11 Oct 2020 17:28:53
User entered 'None (1)'	System	11 Oct 2020 17:28:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-11T12:28:49', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'bb13f024-0648-46ad-ac77-777f3cfb069a'	System	11 Oct 2020 17:28:53
User entered '11 Oct 2020 12:28'	System	11 Oct 2020 17:28:53



**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 6'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50



US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 7'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:10

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50



US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:10

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T10:25:59', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '4d14846f-0270-48b0-a44f-54265d1eba67'	System	07 Oct 2020 15:26:28
User entered 'None (0)'	System	07 Oct 2020 15:26:28



US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T10:26:02', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '4d14846f-0270-48b0-a44f-54265d1eba67'	System	07 Oct 2020 15:26:28
User entered 'None (0)'	System	07 Oct 2020 15:26:28

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T10:26:07', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '4d14846f-0270-48b0-a44f-54265d1eba67'	System	07 Oct 2020 15:26:28
User entered 'None (0)'	System	07 Oct 2020 15:26:28

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T10:26:10', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '4d14846f-0270-48b0-a44f-54265d1eba67'	System	07 Oct 2020 15:26:28
User entered 'None (0)'	System	07 Oct 2020 15:26:28

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T10:26:13', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '4d14846f-0270-48b0-a44f-54265d1eba67'	System	07 Oct 2020 15:26:28
User entered 'None (0)'	System	07 Oct 2020 15:26:28

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T10:26:17', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '4d14846f-0270-48b0-a44f-54265d1eba67'	System	07 Oct 2020 15:26:28
User entered 'None (0)'	System	07 Oct 2020 15:26:28

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T10:26:21', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '4d14846f-0270-48b0-a44f-54265d1eba67'	System	07 Oct 2020 15:26:28
User entered 'No (N)'	System	07 Oct 2020 15:26:28

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T10:26:24', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '4d14846f-0270-48b0-a44f-54265d1eba67'	System	07 Oct 2020 15:26:28
User entered '07 Oct 2020 10:26'	System	07 Oct 2020 15:26:28

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '07 Oct 2020 10:13'	System	07 Oct 2020 15:11:53



**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '07 Oct 2020 12:43'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 1, after vaccination (at home)'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T13:40:59', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6c50f859-285e-4d99-b7d8-8c0b11fb85b1'	System	07 Oct 2020 18:41:40
User entered 'None (0)'	System	07 Oct 2020 18:41:40

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T13:41:02', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6c50f859-285e-4d99-b7d8-8c0b11fb85b1'	System	07 Oct 2020 18:41:40
User entered 'None (0)'	System	07 Oct 2020 18:41:40

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T13:41:04', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6c50f859-285e-4d99-b7d8-8c0b11fb85b1'	System	07 Oct 2020 18:41:40
User entered 'None (0)'	System	07 Oct 2020 18:41:40

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T13:41:06', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6c50f859-285e-4d99-b7d8-8c0b11fb85b1'	System	07 Oct 2020 18:41:40
User entered 'None (0)'	System	07 Oct 2020 18:41:40

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T13:41:08', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6c50f859-285e-4d99-b7d8-8c0b11fb85b1'	System	07 Oct 2020 18:41:40
User entered 'None (0)'	System	07 Oct 2020 18:41:40

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T13:41:10', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6c50f859-285e-4d99-b7d8-8c0b11fb85b1'	System	07 Oct 2020 18:41:40
User entered 'None (0)'	System	07 Oct 2020 18:41:40



US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T13:41:29', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6c50f859-285e-4d99-b7d8-8c0b11fb85b1'	System	07 Oct 2020 18:41:40
User entered 'No (N)'	System	07 Oct 2020 18:41:40

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-07T13:41:32', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '6c50f859-285e-4d99-b7d8-8c0b11fb85b1'	System	07 Oct 2020 18:41:40
User entered '07 Oct 2020 13:41'	System	07 Oct 2020 18:41:40

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '07 Oct 2020 13:38'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '08 Oct 2020 11:59'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 2'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-08T12:02:43', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '545e9504-9780-487f-9b2f-fa8276c52886'	System	08 Oct 2020 17:03:39
User entered 'None (0)'	System	08 Oct 2020 17:03:39

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-08T12:02:45', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '545e9504-9780-487f-9b2f-fa8276c52886'	System	08 Oct 2020 17:03:39
User entered 'None (0)'	System	08 Oct 2020 17:03:39

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-08T12:02:47', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '545e9504-9780-487f-9b2f-fa8276c52886'	System	08 Oct 2020 17:03:39
User entered 'None (0)'	System	08 Oct 2020 17:03:39



US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-08T12:02:50', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '545e9504-9780-487f-9b2f-fa8276c52886'	System	08 Oct 2020 17:03:39
User entered 'None (0)'	System	08 Oct 2020 17:03:39

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:02:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-08T12:02:52', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '545e9504-9780-487f-9b2f-fa8276c52886'	System	08 Oct 2020 17:03:39
User entered 'None (0)'	System	08 Oct 2020 17:03:39

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:02:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-08T12:02:55', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '545e9504-9780-487f-9b2f-fa8276c52886'	System	08 Oct 2020 17:03:39
User entered 'None (0)'	System	08 Oct 2020 17:03:39

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-08T12:02:58', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '545e9504-9780-487f-9b2f-fa8276c52886'	System	08 Oct 2020 17:03:39
User entered 'No (N)'	System	08 Oct 2020 17:03:39

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-08T12:03:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '545e9504-9780-487f-9b2f-fa8276c52886'	System	08 Oct 2020 17:03:39
User entered '08 Oct 2020 12:03'	System	08 Oct 2020 17:03:39

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '08 Oct 2020 12:00'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '09 Oct 2020 11:59'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 3'	System	07 Oct 2020 15:11:53



**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-09T12:03:05', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'a80dcf63-eb80-4a29-a0e0-63088630d5e0'	System	09 Oct 2020 17:03:39
User entered 'None (0)'	System	09 Oct 2020 17:03:39

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-09T12:03:10', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'a80dcf63-eb80-4a29-a0e0-63088630d5e0'	System	09 Oct 2020 17:03:39
User entered 'None (0)'	System	09 Oct 2020 17:03:39

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-09T12:03:15', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'a80dcf63-eb80-4a29-a0e0-63088630d5e0' User entered 'None (0)'	System	09 Oct 2020 17:03:39
	System	09 Oct 2020 17:03:39

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-09T12:03:19', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'a80dcf63-eb80-4a29-a0e0-63088630d5e0' User entered 'None (0)'	System	09 Oct 2020 17:03:39
	System	09 Oct 2020 17:03:39

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-09T12:03:22', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'a80dcf63-eb80-4a29-a0e0-63088630d5e0'	System	09 Oct 2020 17:03:39
User entered 'None (0)'	System	09 Oct 2020 17:03:39

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:10

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-09T12:03:25', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'a80dcf63-eb80-4a29-a0e0-63088630d5e0' User entered 'None (0)'	System	09 Oct 2020 17:03:39
	System	09 Oct 2020 17:03:39

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-09T12:03:30', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'a80dcf63-eb80-4a29-a0e0-63088630d5e0'	System	09 Oct 2020 17:03:39
User entered 'No (N)'	System	09 Oct 2020 17:03:39

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-09T12:03:33', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'a80dcf63-eb80-4a29-a0e0-63088630d5e0'	System	09 Oct 2020 17:03:39
User entered '09 Oct 2020 12:03'	System	09 Oct 2020 17:03:39



**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '09 Oct 2020 12:00'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '10 Oct 2020 11:59'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 4'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-10T13:23:22', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd753f921-fa78-47e2-b710-bcb099f747ee'	System	10 Oct 2020 18:23:46
User entered 'None (0)'	System	10 Oct 2020 18:23:46

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-10T13:23:24', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd753f921-fa78-47e2-b710-bcb099f747ee'	System	10 Oct 2020 18:23:46
User entered 'None (0)'	System	10 Oct 2020 18:23:46

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-10T13:23:27', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd753f921-fa78-47e2-b710-bcb099f747ee'	System	10 Oct 2020 18:23:46
User entered 'None (0)'	System	10 Oct 2020 18:23:46

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-10T13:23:28', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd753f921-fa78-47e2-b710-bcb099f747ee'	System	10 Oct 2020 18:23:46
User entered 'None (0)'	System	10 Oct 2020 18:23:46

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-10T13:23:30', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd753f921-fa78-47e2-b710-bcb099f747ee'	System	10 Oct 2020 18:23:46
User entered 'None (0)'	System	10 Oct 2020 18:23:46



**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-10T13:23:32', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd753f921-fa78-47e2-b710-bcb099f747ee'	System	10 Oct 2020 18:23:46
User entered 'None (0)'	System	10 Oct 2020 18:23:46

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-10T13:23:39', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd753f921-fa78-47e2-b710-bcb099f747ee'	System	10 Oct 2020 18:23:46
User entered 'No (N)'	System	10 Oct 2020 18:23:46

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-10T13:23:41', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd753f921-fa78-47e2-b710-bcb099f747ee'	System	10 Oct 2020 18:23:46
User entered '10 Oct 2020 13:23'	System	10 Oct 2020 18:23:46

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '10 Oct 2020 12:00'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '11 Oct 2020 11:59'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 5'	System	07 Oct 2020 15:11:53

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:10

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-11T12:29:04', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd8902b3a-bf11-47b4-a8f1-96b2a0de11bc'	System	11 Oct 2020 17:29:21
User entered 'None (0)'	System	11 Oct 2020 17:29:21

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:10

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-11T12:29:06', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd8902b3a-bf11-47b4-a8f1-96b2a0de11bc'	System	11 Oct 2020 17:29:21
User entered 'None (0)'	System	11 Oct 2020 17:29:21



US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-11T12:29:08', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd8902b3a-bf11-47b4-a8f1-96b2a0de11bc'	System	11 Oct 2020 17:29:21
User entered 'None (0)'	System	11 Oct 2020 17:29:21

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-11T12:29:10', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd8902b3a-bf11-47b4-a8f1-96b2a0de11bc'	System	11 Oct 2020 17:29:21
User entered 'None (0)'	System	11 Oct 2020 17:29:21

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-11T12:29:11', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd8902b3a-bf11-47b4-a8f1-96b2a0de11bc'	System	11 Oct 2020 17:29:21
User entered 'None (0)'	System	11 Oct 2020 17:29:21

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-11T12:29:13', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd8902b3a-bf11-47b4-a8f1-96b2a0de11bc'	System	11 Oct 2020 17:29:21
User entered 'None (0)'	System	11 Oct 2020 17:29:21

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-11T12:29:15', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd8902b3a-bf11-47b4-a8f1-96b2a0de11bc'	System	11 Oct 2020 17:29:21
User entered 'No (N)'	System	11 Oct 2020 17:29:21

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 10:02:10

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-10-11T12:29:18', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd8902b3a-bf11-47b4-a8f1-96b2a0de11bc'	System	11 Oct 2020 17:29:21
User entered '11 Oct 2020 12:29'	System	11 Oct 2020 17:29:21

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '11 Oct 2020 12:00'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '12 Oct 2020 11:59'	System	07 Oct 2020 15:11:53



**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 6'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50



**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '12 Oct 2020 12:00'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '13 Oct 2020 11:59'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
Data entry locked.	System	07 Oct 2020 15:11:53
User entered 'Day 7'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:10

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:10

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50



US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:10

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

US3862144

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 10:02:10

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 00:46:50

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '13 Oct 2020 12:00'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 10:02:10**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:46:50
User entered '14 Oct 2020 11:59'	System	07 Oct 2020 15:11:53

**US3862144**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:31:27
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4)	14 Oct 2020 18:18:05

**US3862144**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:31:27
User entered '14 Oct 2020'	(b) (4) Shetel Anassi (b) (4)	14 Oct 2020 18:18:05



**US3862144**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:31:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Shetel Anassi (b) (4)	14 Oct 2020 18:18:05

**US3862144**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:31:27
User entered empty.	(b) (4) Shetel Anassi (b) (4)	14 Oct 2020 18:18:05

**US3862144**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:31:27
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4)	14 Oct 2020 18:18:09

**US3862144**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered 'I'	System	14 Oct 2020 18:18:09

**US3862144**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	23 Oct 2020 21:29:26

**US3862144**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '23 Oct 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	23 Oct 2020 21:29:26

**US3862144**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	23 Oct 2020 21:29:26

**US3862144**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	23 Oct 2020 21:29:26



**US3862144**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	23 Oct 2020 21:29:35

**US3862144**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered 'I'	System	23 Oct 2020 21:29:35

**US3862144**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	28 Oct 2020 22:28:27
	(b) (4)	

**US3862144**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered '28 Oct 2020'	(b) (4) Thea Marie Cordero	28 Oct 2020 22:28:27
	(b) (4)	

**US3862144**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Thea Marie Cordero (b) (4)	28 Oct 2020 22:28:27

**US3862144**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered empty.	(b) (4) Thea Marie Cordero	28 Oct 2020 22:28:27
	(b) (4)	

**US3862144**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:03
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	28 Oct 2020 22:28:33
	(b) (4)	

**US3862144**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered 'I'	System	28 Oct 2020 22:28:33



**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 16:08:10

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '5 Nov 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 16:08:10

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[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 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 16:08:10

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered 'VISIT3'	System	05 Nov 2020 16:08:10

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4) (b) (4)	05 Nov 2020 18:56:04

US3862144

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '5 Nov 2020'	(b) (4) Trent Davis (b) (4) (b) (4)	05 Nov 2020 18:56:04

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '08:30'	(b) (4) Trent Davis (b) (4) (b) (4)	05 Nov 2020 18:56:04

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered '5 Nov 2020 08:30'	System	05 Nov 2020 18:56:04



US3862144

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '097.9' F	(b) (4) Trent Davis (b) (4) (b) (4)	05 Nov 2020 18:56:04

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Other (Other)'	(b) (4) Trent Davis (b) (4) (b) (4)	05 Nov 2020 18:56:04

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'temporal'	(b) (4) Trent Davis (b) (4) (b) (4)	05 Nov 2020 18:56:04

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '083'	(b) (4) Trent Davis (b) (4) (b) (4)	05 Nov 2020 18:56:04

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered 'bpm'	System	05 Nov 2020 18:56:04

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '016'	(b) (4) Trent Davis (b) (4)	05 Nov 2020 18:56:04

US3862144

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered 'breaths/min'	System	05 Nov 2020 18:56:04

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '131'	(b) (4) Trent Davis (b) (4) (b) (4)	05 Nov 2020 18:56:04



**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered 'mmHg'	System	05 Nov 2020 18:56:04

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '099'	(b) (4) Trent Davis (b) (4)	05 Nov 2020 18:56:04

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered 'mmHg'	System	05 Nov 2020 18:56:04

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:02:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 16:08:02

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:02:10**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '5 Nov 2020'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 16:08:02

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	05 Nov 2020 18:56:24



**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '5 Nov 2020'	(b) (4) Trent Davis (b) (4) (b) (4)	05 Nov 2020 18:56:24

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered '09:40'	(b) (4) Trent Davis (b) (4) (b) (4)	05 Nov 2020 18:56:24

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered '5 Nov 2020 09:40'	System	05 Nov 2020 18:56:24

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User signature succeeded.	Hana El Sahly (b) (4)	13 Feb 2021 00:53:22
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 16:08:14

**US3862144**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:57
User entered 'I'	System	05 Nov 2020 16:08:14

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 64'	System	08 Sep 2020 20:44:59

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Have you been exposed to someone with 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 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Please 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 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Please 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 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Please 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 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51
Data entry locked.	System	08 Sep 2020 20:44:59
User entered '08 Nov 2020 00:01'	System	08 Sep 2020 20:44:59



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51
Data entry locked.	System	08 Sep 2020 20:44:59
User entered '12 Nov 2020 23:59'	System	08 Sep 2020 20:44:59

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51
Data entry locked.	System	08 Sep 2020 20:44:59
User entered 'Day 71'	System	08 Sep 2020 20:44:59

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Have you been exposed to someone with 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 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Please 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 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Please 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 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Please 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 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51

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

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51
Data entry locked.	System	08 Sep 2020 20:44:59
User entered '15 Nov 2020 00:01'	System	08 Sep 2020 20:44:59

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 06:15:51
Data entry locked.	System	08 Sep 2020 20:44:59
User entered '19 Nov 2020 23:59'	System	08 Sep 2020 20:44:59

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '19 Nov 2020 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '23 Nov 2020 23:59'	System	20 Nov 2020 06:15:51



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 (a7b11825c8a473b3)', Time: '2020-11-29T20:47:33', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '2d5953ae-153b-41b5-8511-6de32e4eccc0'	System	30 Nov 2020 02:48:00
User entered 'No (N)'	System	30 Nov 2020 02:48:00

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Have you been exposed to someone with 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 (a7b11825c8a473b3)', Time: '2020-11-29T20:47:42', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '2d5953ae-153b-41b5-8511-6de32e4eccc0'	System	30 Nov 2020 02:48:00
User entered 'No (N)'	System	30 Nov 2020 02:48:00

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-11-29T20:47:54', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '2d5953ae-153b-41b5-8511-6de32e4eccc0'	System	30 Nov 2020 02:48:00
User entered '29 Nov 2020 20:47:54'	System	30 Nov 2020 02:48:00

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '26 Nov 2020 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '30 Nov 2020 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 (a7b11825c8a473b3)', Time: '2020-12-03T00:01:59', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8c045c6d-50f7-4fb0-b720-a6112b055e64'	System	03 Dec 2020 06:02:23
User entered 'No (N)'	System	03 Dec 2020 06:02:23



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Have you been exposed to someone with 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 (a7b11825c8a473b3)', Time: '2020-12-03T00:02:06', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8c045c6d-50f7-4fb0-b720-a6112b055e64'	System	03 Dec 2020 06:02:23
User entered 'No (N)'	System	03 Dec 2020 06:02:23

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-12-03T00:02:11', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '8c045c6d-50f7-4fb0-b720-a6112b055e64'	System	03 Dec 2020 06:02:23
User entered '03 Dec 2020 00:02:11'	System	03 Dec 2020 06:02:23

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '03 Dec 2020 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '07 Dec 2020 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 (a7b11825c8a473b3)', Time: '2020-12-10T09:40:25', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '893ea0ec-f8cd-4bbf-a7a2-1414c96d8596'	System	10 Dec 2020 15:40:43
User entered 'No (N)'	System	10 Dec 2020 15:40:43

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Have you been exposed to someone with 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 (a7b11825c8a473b3)', Time: '2020-12-10T09:40:31', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '893ea0ec-f8cd-4bbf-a7a2-1414c96d8596'	System	10 Dec 2020 15:40:43
User entered 'No (N)'	System	10 Dec 2020 15:40:43

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-12-10T09:40:35', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '893ea0ec-f8cd-4bbf-a7a2-1414c96d8596'	System	10 Dec 2020 15:40:43
User entered '10 Dec 2020 09:40:35'	System	10 Dec 2020 15:40:43



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '10 Dec 2020 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '14 Dec 2020 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 (a7b11825c8a473b3)', Time: '2020-12-17T00:02:03', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'db735c2d-fa5d-42c5-a1d4-d776d42219aa'	System	17 Dec 2020 06:02:36
User entered 'No (N)'	System	17 Dec 2020 06:02:36

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Have you been exposed to someone with 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 (a7b11825c8a473b3)', Time: '2020-12-17T00:02:09', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'db735c2d-fa5d-42c5-a1d4-d776d42219aa'	System	17 Dec 2020 06:02:36
User entered 'No (N)'	System	17 Dec 2020 06:02:36

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-12-17T00:02:16', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'db735c2d-fa5d-42c5-a1d4-d776d42219aa'	System	17 Dec 2020 06:02:36
User entered '17 Dec 2020 00:02:16'	System	17 Dec 2020 06:02:36

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '17 Dec 2020 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '21 Dec 2020 23:59'	System	20 Nov 2020 06:15:51



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 (a7b11825c8a473b3)', Time: '2020-12-24T00:02:25', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'a42050d8-a407-4c43-ae78-0eb7b9056205'	System	24 Dec 2020 06:02:54
User entered 'No (N)'	System	24 Dec 2020 06:02:54

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Have you been exposed to someone with 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 (a7b11825c8a473b3)', Time: '2020-12-24T00:02:38', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'a42050d8-a407-4c43-ae78-0eb7b9056205'	System	24 Dec 2020 06:02:54
User entered 'No (N)'	System	24 Dec 2020 06:02:54

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-12-24T00:02:46', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'a42050d8-a407-4c43-ae78-0eb7b9056205'	System	24 Dec 2020 06:02:54
User entered '24 Dec 2020 00:02:46'	System	24 Dec 2020 06:02:54

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '24 Dec 2020 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '28 Dec 2020 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 (a7b11825c8a473b3)', Time: '2020-12-31T00:15:20', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd60682f6-182d-4333-9f91-258beb33e19b'	System	31 Dec 2020 06:15:31
User entered 'No (N)'	System	31 Dec 2020 06:15:31



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Have you been exposed to someone with 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 (a7b11825c8a473b3)', Time: '2020-12-31T00:15:23', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd60682f6-182d-4333-9f91-258beb33e19b'	System	31 Dec 2020 06:15:31
User entered 'No (N)'	System	31 Dec 2020 06:15:31

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2020-12-31T00:15:27', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'd60682f6-182d-4333-9f91-258beb33e19b'	System	31 Dec 2020 06:15:31
User entered '31 Dec 2020 00:15:27'	System	31 Dec 2020 06:15:31

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '31 Dec 2020 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '04 Jan 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 (a7b11825c8a473b3)', Time: '2021-01-07T00:02:14', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '28d768ff-7d0d-4807-acef-a3aef1947c0e'	System	07 Jan 2021 06:02:32
User entered 'No (N)'	System	07 Jan 2021 06:02:32

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Have you been exposed to someone with 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 (a7b11825c8a473b3)', Time: '2021-01-07T00:02:20', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '28d768ff-7d0d-4807-acef-a3aef1947c0e'	System	07 Jan 2021 06:02:32
User entered 'No (N)'	System	07 Jan 2021 06:02:32

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2021-01-07T00:02:23', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '28d768ff-7d0d-4807-acef-a3aef1947c0e'	System	07 Jan 2021 06:02:32
User entered '07 Jan 2021 00:02:23'	System	07 Jan 2021 06:02:32



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '07 Jan 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '11 Jan 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 (a7b11825c8a473b3)', Time: '2021-01-14T08:53:54', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '3fff1cbe-65be-461e-9d88-be09bd59665d'	System	14 Jan 2021 14:54:07
User entered 'No (N)'	System	14 Jan 2021 14:54:07

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Have you been exposed to someone with 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 (a7b11825c8a473b3)', Time: '2021-01-14T08:53:58', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '3fff1cbe-65be-461e-9d88-be09bd59665d'	System	14 Jan 2021 14:54:07
User entered 'No (N)'	System	14 Jan 2021 14:54:07

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a7b11825c8a473b3)', Time: '2021-01-14T08:54:02', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '3fff1cbe-65be-461e-9d88-be09bd59665d' User entered '14 Jan 2021 08:54:02'	System	14 Jan 2021 14:54:07
	System	14 Jan 2021 14:54:07

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '14 Jan 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '18 Jan 2021 23:59'	System	20 Nov 2020 06:15:51



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 (17cdee35c442c06d)', Time: '2021-01-25T12:52:31', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'f5734afd-6cad-48b8-a943-595e70d299c7'	System	25 Jan 2021 18:52:42
User entered 'No (N)'	System	25 Jan 2021 18:52:42

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Have you been exposed to someone with 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 (17cdee35c442c06d)', Time: '2021-01-25T12:52:35', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'f5734afd-6cad-48b8-a943-595e70d299c7'	System	25 Jan 2021 18:52:42
User entered 'No (N)'	System	25 Jan 2021 18:52:42

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17cdee35c442c06d)', Time: '2021-01-25T12:52:38', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'f5734afd-6cad-48b8-a943-595e70d299c7' User entered '25 Jan 2021 12:52:38'	System	25 Jan 2021 18:52:42
	System	25 Jan 2021 18:52:42

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '21 Jan 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '25 Jan 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 (17cdee35c442c06d)', Time: '2021-01-30T12:00:56', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '12e62724-a754-4d8d-a16e-f6bb51ee9b88'	System	30 Jan 2021 18:01:48
User entered 'No (N)'	System	30 Jan 2021 18:01:48



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Have you been exposed to someone with 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 (17cdee35c442c06d)', Time: '2021-01-30T12:01:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '12e62724-a754-4d8d-a16e-f6bb51ee9b88'	System	30 Jan 2021 18:01:48
User entered 'No (N)'	System	30 Jan 2021 18:01:48

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17cdee35c442c06d)', Time: '2021-01-30T12:01:03', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '12e62724-a754-4d8d-a16e-f6bb51ee9b88' User entered '30 Jan 2021 12:01:03'	System	30 Jan 2021 18:01:48
	System	30 Jan 2021 18:01:48

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '28 Jan 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '01 Feb 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 (17cdee35c442c06d)', Time: '2021-02-04T09:18:45', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '0dc87e28-c67e-4351-8fc8-1ab278d95ca1'	System	04 Feb 2021 15:18:59
User entered 'No (N)'	System	04 Feb 2021 15:18:59

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Have you been exposed to someone with 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 (17cdee35c442c06d)', Time: '2021-02-04T09:18:50', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '0dc87e28-c67e-4351-8fc8-1ab278d95ca1'	System	04 Feb 2021 15:18:59
User entered 'No (N)'	System	04 Feb 2021 15:18:59

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17cdee35c442c06d)', Time: '2021-02-04T09:18:55', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '0dc87e28-c67e-4351-8fc8-1ab278d95ca1'	System	04 Feb 2021 15:18:59
User entered '04 Feb 2021 09:18:55'	System	04 Feb 2021 15:18:59



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '04 Feb 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '08 Feb 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '11 Feb 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '15 Feb 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '18 Feb 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '22 Feb 2021 23:59'	System	20 Nov 2020 06:15:51



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '25 Feb 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '01 Mar 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '04 Mar 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '08 Mar 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 (17cdee35c442c06d)', Time: '2021-03-15T16:31:39-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '2fced373-d7ad-4113-ae57-db447abd9228'	System	15 Mar 2021 21:31:50
User entered 'No (N)'	System	15 Mar 2021 21:31:50



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Have you been exposed to someone with 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 (17cdee35c442c06d)', Time: '2021-03-15T16:31:43-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '2fced373-d7ad-4113-ae57-db447abd9228'	System	15 Mar 2021 21:31:50
User entered 'No (N)'	System	15 Mar 2021 21:31:50

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17cdee35c442c06d)', Time: '2021-03-15T16:31:47-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '2fced373-d7ad-4113-ae57-db447abd9228' User entered '15 Mar 2021 16:31:47'	System	15 Mar 2021 21:31:50
	System	15 Mar 2021 21:31:50

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '11 Mar 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '15 Mar 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 (17cdee35c442c06d)', Time: '2021-03-19T01:24:08-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '86527071-fa74-4ef0-853d-b3b14b1d971a'	System	19 Mar 2021 06:24:19
User entered 'No (N)'	System	19 Mar 2021 06:24:19

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Have you been exposed to someone with 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 (17cdee35c442c06d)', Time: '2021-03-19T01:24:12-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '86527071-fa74-4ef0-853d-b3b14b1d971a'	System	19 Mar 2021 06:24:19
User entered 'No (N)'	System	19 Mar 2021 06:24:19

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17cdee35c442c06d)', Time: '2021-03-19T01:24:15-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '86527071-fa74-4ef0-853d-b3b14b1d971a' User entered '19 Mar 2021 01:24:15'	System	19 Mar 2021 06:24:19
	System	19 Mar 2021 06:24:19



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '18 Mar 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '22 Mar 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 (17cdee35c442c06d)', Time: '2021-03-25T09:49:24-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '94ef38e8-03ce-4a20-80dd-675d208d614a'	System	25 Mar 2021 14:49:33
User entered 'No (N)'	System	25 Mar 2021 14:49:33

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Have you been exposed to someone with 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 (17cdee35c442c06d)', Time: '2021-03-25T09:49:27-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '94ef38e8-03ce-4a20-80dd-675d208d614a'	System	25 Mar 2021 14:49:33
User entered 'No (N)'	System	25 Mar 2021 14:49:33

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17cdee35c442c06d)', Time: '2021-03-25T09:49:29-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '94ef38e8-03ce-4a20-80dd-675d208d614a' User entered '25 Mar 2021 09:49:29'	System	25 Mar 2021 14:49:33
	System	25 Mar 2021 14:49:33

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '25 Mar 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '29 Mar 2021 23:59'	System	20 Nov 2020 06:15:51



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 (17cdee35c442c06d)', Time: '2021-04-01T00:24:00-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '7016daec-37f7-4b6a-b7df-f2f78e5429a8' User entered 'No (N)'	System	01 Apr 2021 05:24:19
	System	01 Apr 2021 05:24:19

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Have you been exposed to someone with 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 (17cdee35c442c06d)', Time: '2021-04-01T00:24:08-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '7016daec-37f7-4b6a-b7df-f2f78e5429a8'	System	01 Apr 2021 05:24:19
User entered 'No (N)'	System	01 Apr 2021 05:24:19

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17cdee35c442c06d)', Time: '2021-04-01T00:24:12-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '7016daec-37f7-4b6a-b7df-f2f78e5429a8'	System	01 Apr 2021 05:24:19
User entered '01 Apr 2021 00:24:12'	System	01 Apr 2021 05:24:19

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '01 Apr 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '05 Apr 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 (17cdee35c442c06d)', Time: '2021-04-08T08:08:42-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'fdd26541-dd05-43b2-810b-7f784b37e9b1'	System	08 Apr 2021 13:09:01
User entered 'No (N)'	System	08 Apr 2021 13:09:01



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Have you been exposed to someone with 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 (17cdee35c442c06d)', Time: '2021-04-08T08:08:48-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'fdd26541-dd05-43b2-810b-7f784b37e9b1'	System	08 Apr 2021 13:09:01
User entered 'No (N)'	System	08 Apr 2021 13:09:01

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17cdee35c442c06d)', Time: '2021-04-08T08:08:57-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'fdd26541-dd05-43b2-810b-7f784b37e9b1'	System	08 Apr 2021 13:09:01
User entered '08 Apr 2021 08:08:57'	System	08 Apr 2021 13:09:01

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '08 Apr 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '12 Apr 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 (17cdee35c442c06d)', Time: '2021-04-15T00:02:13-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'a21ccd7e-d2c9-41c3-8d08-8c44e5312c83' User entered 'No (N)'	System	15 Apr 2021 05:02:43
	System	15 Apr 2021 05:02:43

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Have you been exposed to someone with 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 (17cdee35c442c06d)', Time: '2021-04-15T00:02:20-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'a21ccd7e-d2c9-41c3-8d08-8c44e5312c83'	System	15 Apr 2021 05:02:43
User entered 'No (N)'	System	15 Apr 2021 05:02:43

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17cdee35c442c06d)', Time: '2021-04-15T00:02:33-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'a21ccd7e-d2c9-41c3-8d08-8c44e5312c83'	System	15 Apr 2021 05:02:43
User entered '15 Apr 2021 00:02:33'	System	15 Apr 2021 05:02:43



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '15 Apr 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '19 Apr 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 (17cdee35c442c06d)', Time: '2021-04-22T00:40:14-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '2a043c9b-4e50-494c-bda9-cbd59fc6367f' User entered 'No (N)'	System	22 Apr 2021 05:40:39
	System	22 Apr 2021 05:40:39

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

Have you been exposed to someone with 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 (17cdee35c442c06d)', Time: '2021-04-22T00:40:30-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '2a043c9b-4e50-494c-bda9-cbd59fc6367f' User entered 'No (N)'	System	22 Apr 2021 05:40:39

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17cdee35c442c06d)', Time: '2021-04-22T00:40:35-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: '2a043c9b-4e50-494c-bda9-cbd59fc6367f' User entered '22 Apr 2021 00:40:35'	System	22 Apr 2021 05:40:39
	System	22 Apr 2021 05:40:39

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '22 Apr 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '26 Apr 2021 23:59'	System	20 Nov 2020 06:15:51



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[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 (17cdee35c442c06d)', Time: '2021-04-29T06:01:17-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'af950ac0-043a-4258-9184-d72663f37ac8'	System	29 Apr 2021 11:01:40
User entered 'No (N)'	System	29 Apr 2021 11:01:40

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Have you been exposed to someone with 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 (17cdee35c442c06d)', Time: '2021-04-29T06:01:22-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'af950ac0-043a-4258-9184-d72663f37ac8'	System	29 Apr 2021 11:01:40
User entered 'No (N)'	System	29 Apr 2021 11:01:40

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17cdee35c442c06d)', Time: '2021-04-29T06:01:31-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'af950ac0-043a-4258-9184-d72663f37ac8' User entered '29 Apr 2021 06:01:31'	System	29 Apr 2021 11:01:40
	System	29 Apr 2021 11:01:40

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '29 Apr 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '03 May 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '06 May 2021 00:01'	System	20 Nov 2020 06:15:51



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '10 May 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '13 May 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '17 May 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '20 May 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '24 May 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 06:15:51



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '27 May 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '31 May 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '03 Jun 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '07 Jun 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '10 Jun 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '14 Jun 2021 23:59'	System	20 Nov 2020 06:15:51



**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 06:15:51

**US3862144**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '17 Jun 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '21 Jun 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '24 Jun 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '28 Jun 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '01 Jul 2021 00:01'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '05 Jul 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '08 Jul 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '12 Jul 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '15 Jul 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '19 Jul 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '22 Jul 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '26 Jul 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '29 Jul 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '02 Aug 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '05 Aug 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '09 Aug 2021 23:59'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '12 Aug 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '16 Aug 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '19 Aug 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '23 Aug 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '26 Aug 2021 00:01'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '30 Aug 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '02 Sep 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '06 Sep 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '09 Sep 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '13 Sep 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '16 Sep 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '20 Sep 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '23 Sep 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '27 Sep 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '30 Sep 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '04 Oct 2021 23:59'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '07 Oct 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '11 Oct 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '14 Oct 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '18 Oct 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '21 Oct 2021 00:01'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '25 Oct 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '28 Oct 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '01 Nov 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '04 Nov 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '08 Nov 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '11 Nov 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '15 Nov 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '18 Nov 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '22 Nov 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '25 Nov 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '29 Nov 2021 23:59'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '02 Dec 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '06 Dec 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '09 Dec 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '13 Dec 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '16 Dec 2021 00:01'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '20 Dec 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '23 Dec 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '27 Dec 2021 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '30 Dec 2021 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '03 Jan 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '06 Jan 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '10 Jan 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '13 Jan 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '17 Jan 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '20 Jan 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '24 Jan 2022 23:59'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '27 Jan 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '31 Jan 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '03 Feb 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '07 Feb 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '10 Feb 2022 00:01'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '14 Feb 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '17 Feb 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '21 Feb 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '24 Feb 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '28 Feb 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '03 Mar 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '07 Mar 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '10 Mar 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '14 Mar 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '17 Mar 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '21 Mar 2022 23:59'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '24 Mar 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '28 Mar 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '31 Mar 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '04 Apr 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '07 Apr 2022 00:01'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '11 Apr 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '14 Apr 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '18 Apr 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '21 Apr 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '25 Apr 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '28 Apr 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '02 May 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '05 May 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '09 May 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '12 May 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '16 May 2022 23:59'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '19 May 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '23 May 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '26 May 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '30 May 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '02 Jun 2022 00:01'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '06 Jun 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '09 Jun 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '13 Jun 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '16 Jun 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '20 Jun 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '23 Jun 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '27 Jun 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '30 Jun 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '04 Jul 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '07 Jul 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '11 Jul 2022 23:59'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '14 Jul 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '18 Jul 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '21 Jul 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '25 Jul 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '28 Jul 2022 00:01'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '01 Aug 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '04 Aug 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '08 Aug 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '11 Aug 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '15 Aug 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '18 Aug 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '22 Aug 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '25 Aug 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '29 Aug 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '01 Sep 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '05 Sep 2022 23:59'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '08 Sep 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '12 Sep 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '15 Sep 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '19 Sep 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '22 Sep 2022 00:01'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '26 Sep 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '29 Sep 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '03 Oct 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '06 Oct 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '10 Oct 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '13 Oct 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '17 Oct 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '20 Oct 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '24 Oct 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '27 Oct 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '31 Oct 2022 23:59'	System	20 Nov 2020 06:15:51



**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '03 Nov 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '07 Nov 2022 23:59'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '10 Nov 2022 00:01'	System	20 Nov 2020 06:15:51

**US3862144**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 10:02:10**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 06:15:51
Amendment Manager: User entered '14 Nov 2022 23:59'	System	20 Nov 2020 06:15:51

US3862144

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 10:02:10**

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 21:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17cdee35c442c06d)', Time: '2021-03-15T16:32:00-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'a2501ea3-1250-4bb4-b6e4-c1317629a6ed' User entered 'No (N)'	System	15 Mar 2021 21:32:09
	System	15 Mar 2021 21:32:09

**US3862144**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 21:24:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (17cdee35c442c06d)', Time: '2021-03-15T16:32:05-05:00', User OID: 'PatientReportedOutcome (US3862144)', ODM File OID: 'a2501ea3-1250-4bb4-b6e4-c1317629a6ed' User entered '15 Mar 2021 16:32:05'	System	15 Mar 2021 21:32:09
	System	15 Mar 2021 21:32:09



**US3862144**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:31:27
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	04 Dec 2020 16:43:59

**US3862144**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:31:27
User entered '2 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Carrie Kibler (b) (4)	04 Dec 2020 16:44:22
User entered '3 Dec 2020'	(b) (4)	
	Carrie Kibler (b) (4)	04 Dec 2020 16:43:59
	(b) (4)	

**US3862144**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:31:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	04 Dec 2020 16:43:59

**US3862144**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:31:27
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	04 Dec 2020 16:43:59

**US3862144**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User signature succeeded.	Hana El Sahly (b) (4)	05 Mar 2021 22:31:27
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	04 Dec 2020 16:44:02

**US3862144**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Mar 2021 01:58:35
User entered 'I'	System	04 Dec 2020 16:44:02

**US3862144**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	08 Jan 2021 22:47:58

**US3862144**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '08 Jan 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	08 Jan 2021 22:47:58



**US3862144**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	08 Jan 2021 22:47:58

**US3862144**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Carrie Kibler (b) (4) (b) (4)	08 Jan 2021 22:47:58

**US3862144**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	08 Jan 2021 22:48:04

**US3862144**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:12
User entered 'I'	System	08 Jan 2021 22:48:04

**US3862144**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	08 Mar 2021 22:35:43
	(b) (4)	

**US3862144**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '5 Feb 2021'	(b) (4) Thea Marie Cordero	08 Mar 2021 22:35:43
	(b) (4)	

**US3862144**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Thea Marie Cordero	08 Mar 2021 22:35:43
	(b) (4)	

**US3862144**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Thea Marie Cordero	08 Mar 2021 22:35:43
	(b) (4)	



**US3862144**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	08 Mar 2021 22:35:48
	(b) (4)	

**US3862144**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:12
User entered 'I'	System	08 Mar 2021 22:35:48

**US3862144**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	08 Mar 2021 22:35:59
	(b) (4)	

**US3862144**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '08 Mar 2021' reason for change: Data Entry Error	(b) (4)	12 Mar 2021 22:51:37
User entered '8 Mar 2021'	Carrie Kibler (b) (4)	08 Mar 2021 22:35:59
	Thea Marie Cordero (b) (4)	

**US3862144**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Thea Marie Cordero	08 Mar 2021 22:35:59
	(b) (4)	

**US3862144**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Thea Marie Cordero	08 Mar 2021 22:35:59
	(b) (4)	

**US3862144**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	08 Mar 2021 22:36:04
	(b) (4)	

**US3862144**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:36:12
User entered 'I'	System	08 Mar 2021 22:36:04



**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Apr 2021 15:54:06

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
User entered '05 Apr 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Apr 2021 15:54:06

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Apr 2021 15:54:06

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User entered 'VISIT4'	System	05 Apr 2021 15:54:06

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Apr 2021 15:54:26

US3862144

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:10

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
User entered '05 Apr 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Apr 2021 15:54:26

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
User entered '09:05'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Apr 2021 15:54:26

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User entered '05 Apr 2021 09:05'	System	05 Apr 2021 15:54:26



US3862144

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 10:02:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
User entered '97.4' F	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Apr 2021 15:54:26

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
User entered 'Other (Other)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Apr 2021 15:54:26

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
User entered 'temporal'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Apr 2021 15:54:26

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
User entered '81'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Apr 2021 15:54:26

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User entered 'bpm'	System	05 Apr 2021 15:54:26

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
User entered '15'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Apr 2021 15:54:26

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User entered 'breaths/min'	System	05 Apr 2021 15:54:26

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
User entered '119'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Apr 2021 15:54:26



**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User entered 'mmHg'	System	05 Apr 2021 15:54:26

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
User entered '84'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Apr 2021 15:54:26

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User entered 'mmHg'	System	05 Apr 2021 15:54:26

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:02:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Apr 2021 15:54:32

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:02:10**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
User entered '05 Apr 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Apr 2021 15:54:32

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Apr 2021 15:54:39



**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
User entered '05 Apr 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Apr 2021 15:54:39

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
User entered '09:39'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Apr 2021 15:54:39

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User entered '05 Apr 2021 09:39'	System	05 Apr 2021 15:54:39

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Apr 2021 15:55:30

**US3862144**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:53:13
User entered 'I'	System	05 Apr 2021 15:55:30

US3862144

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 10:02:10

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 22:58:55
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:27:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 05:20:34
Query 'Data is required. Please complete.' answered with 'data entered in error ' (Site from System).	(b) (4), (b) (6)	26 Mar 2021 22:07:40
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Mar 2021 22:07:37
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	26 Mar 2021 22:07:37
User entered 'No (N)'		24 Mar 2021 21:16:03

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 17:49:13

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '25 Jan 2021'	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 17:49:13



**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 17:49:13

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'UNBLND_DECIDE'	System	25 Jan 2021 17:49:13

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:02:10**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '25 Jan 2021'	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 18:28:18
	(b) (4)	

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:02:10**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:35:37

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:02:10**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 18:28:18

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:02:10**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 08:35:37

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:02:10**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '25 Jan 2021'	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 18:28:18

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:02:10**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Placebo (Placebo)'	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 18:28:18



**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:02:10**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Placebo (Placebo)'	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 18:28:18

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:02:10**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Placebo (Placebo)'	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 18:28:18

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:02:10**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 18:28:18

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:02:10**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'I'	System	25 Jan 2021 18:28:18

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 10:02:10**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'I'	System	25 Jan 2021 18:28:18

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 10:02:10**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered missing code ND - Not Done.	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 19:06:40

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 10:02:10**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered missing code ND - Not Done.	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 19:06:40

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 10:02:10**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered empty.	System	25 Jan 2021 19:06:40
DataPoint set to visible.	System	25 Jan 2021 18:28:18



**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 10:02:10**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered missing code ND - Not Done.	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 19:06:40

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 10:02:10**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered missing code ND - Not Done.	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 19:06:40
	(b) (4)	

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 10:02:10**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered empty.	System	25 Jan 2021 19:06:40
DataPoint set to visible.	System	25 Jan 2021 18:28:18

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User accepted default value 'Pre-Dose (PREDOSE)'	Carrie Kibler (b) (4)	25 Jan 2021 19:06:40
	(b) (4)	

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 19:06:40

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '25 Jan 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 19:06:40

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '11:48'	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 19:06:40
	(b) (4)	

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered '25 Jan 2021 11:48'	System	25 Jan 2021 19:06:40



**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '97.6' F	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 19:06:40
	(b) (4)	

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Other (Other)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 19:06:40

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'temporal'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 19:06:40

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '100'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 19:06:40

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'bpm'	System	25 Jan 2021 19:06:40

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '16'	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 19:06:40

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'breaths/min'	System	25 Jan 2021 19:06:40

US3862144

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 10:02:10

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '117'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 19:06:40



**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'mmHg'	System	25 Jan 2021 19:06:40

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '88'	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 19:06:40

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'mmHg'	System	25 Jan 2021 19:06:40

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 10:02:10**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered missing code ND - Not Done.	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 19:06:40

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 10:02:10**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered missing code ND - Not Done.	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 19:06:40

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 10:02:10**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered empty.	System	25 Jan 2021 19:06:40
DataPoint set to visible.	System	25 Jan 2021 18:28:18

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User accepted default value 'Post-Dose (POSTDOSE)'	Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 19:48:25

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 19:48:25



**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '25 Jan 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 19:48:25

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '13:32'	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 19:48:25

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered '25 Jan 2021 13:32'	System	25 Jan 2021 19:48:25

US3862144

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '97.6' F	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 19:48:25

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Other (Other)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 19:48:25

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'temporal'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 19:48:25

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '91'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 19:48:25

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'bpm'	System	25 Jan 2021 19:48:25



**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '16'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 19:48:25

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'breaths/min'	System	25 Jan 2021 19:48:25

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '132'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 19:48:25

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'mmHg'	System	25 Jan 2021 19:48:25

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '89'	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 19:48:25

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'mmHg'	System	25 Jan 2021 19:48:25

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:02:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 18:28:33

US3862144

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 10:02:10

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '25 Jan 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 18:28:33



US3862144

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:10

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 19:06:03
	(b) (4)	

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 19:06:03

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 19:06:03
	(b) (4)	

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'mRNA-1273'	System	25 Jan 2021 19:06:03
DataPoint set to visible.	System	25 Jan 2021 18:28:18

US3862144

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:10

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '25 Jan 2021'	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 19:06:03
	(b) (4)	

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '13:02'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 19:06:03

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered '25 Jan 2021 13:02'	System	25 Jan 2021 19:06:03

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Left Arm (LEFT ARM)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 19:06:03



**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'ONCE'	System	25 Jan 2021 19:06:03

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'INTRAMUSCULAR'	System	25 Jan 2021 19:06:03

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 17:58:25

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '25 Jan 2021'	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 17:58:25
	(b) (4)	

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '11:56'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 17:58:25

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered '25 Jan 2021 11:56'	System	25 Jan 2021 17:58:25

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 10:02:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 17:58:16

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 10:02:10**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '25 Jan 2021'	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 17:58:16



**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 10:02:10**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '11:53'	(b) (4) Carrie Kibler (b) (4) (b) (4)	25 Jan 2021 17:58:16

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 10:02:10**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered '25 Jan 2021 11:53'	System	25 Jan 2021 17:58:16

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	25 Jan 2021 18:28:40

**US3862144**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'I'	System	25 Jan 2021 18:28:40

**US3862144**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	02 Feb 2021 14:46:21
	(b) (4)	

**US3862144**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '2 Feb 2021'	(b) (4) Thea Marie Cordero	02 Feb 2021 14:46:21
	(b) (4)	

**US3862144**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Thea Marie Cordero	02 Feb 2021 14:46:21
	(b) (4)	

**US3862144**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Thea Marie Cordero	02 Feb 2021 14:46:21
	(b) (4)	



**US3862144**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	02 Feb 2021 14:46:26
	(b) (4)	

**US3862144**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'I'	System	02 Feb 2021 14:46:26

**US3862144**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'I'	System	02 Feb 2021 14:46:26
DataPoint set to visible.	System	02 Feb 2021 14:46:26

**US3862144**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	01 Mar 2021 15:19:47

**US3862144**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '01 Mar 2021'	(b) (4) Carrie Kibler (b) (4)	01 Mar 2021 15:19:47
	(b) (4)	

**US3862144**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Clinic (Clinic)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	01 Mar 2021 15:19:47

**US3862144**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'OLD29'	System	01 Mar 2021 15:19:47

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User accepted default value 'Pre-Dose (PREDOSE)'	Shetel Anassi (b) (4)	01 Mar 2021 20:13:03



**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '1 Mar 2021'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '10:01'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered '1 Mar 2021 10:01'	System	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '097.9' F	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Other (Other)'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Temporal'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '068'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:03



**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'bpm'	System	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '012'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'breaths/min'	System	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '134'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'mmHg'	System	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '093'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'mmHg'	System	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User accepted default value 'Post-Dose (POSTDOSE)'	Shetel Anassi (b) (4)	01 Mar 2021 20:13:03



**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '1 Mar 2021'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:03

US3862144

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Mar 2021 20:13:14
Query 'Data is required. Please provide.' answered by System data change (Site from System).	System	01 Mar 2021 20:13:14
User entered '11:30' reason for change: Data Entry Error	Shetel Anassi (b) (4)	01 Mar 2021 20:13:14
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4)	01 Mar 2021 20:13:03
User entered empty.	Shetel Anassi (b) (4)	01 Mar 2021 20:13:03
	(b) (4)	

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered '1 Mar 2021 11:30'	System	01 Mar 2021 20:13:14
User entered empty.	System	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '097.6' F	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Other (Other)'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'temporal'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '074'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:03



**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'bpm'	System	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '012'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:03

US3862144

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 10:02:10

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'breaths/min'	System	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '138'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'mmHg'	System	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '095'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'mmHg'	System	01 Mar 2021 20:13:03

**US3862144**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:02:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	01 Mar 2021 15:19:54



**US3862144**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:02:10**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '01 Mar 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	01 Mar 2021 15:19:54

**US3862144**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:38

US3862144

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:10

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:38

US3862144

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:10

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:38
	(b) (4)	

**US3862144**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'mRNA-1273'	System	01 Mar 2021 20:13:38
DataPoint set to visible.	System	02 Feb 2021 14:46:26

**US3862144**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '1 Mar 2021'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:38

**US3862144**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '11:00'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:38

**US3862144**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered '1 Mar 2021 11:00'	System	01 Mar 2021 20:13:38



US3862144

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:10

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Left Arm (LEFT ARM)'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:38

US3862144

Folder: OL-D29 (1)

Form: Exposure

Generated On: 10 Jun 2021 10:02:10

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'ONCE'	System	01 Mar 2021 20:13:38

**US3862144**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 10:02:10**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'INTRAMUSCULAR'	System	01 Mar 2021 20:13:38

**US3862144**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Shetel Anassi (b) (4)	01 Mar 2021 20:13:45

**US3862144**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'I'	System	01 Mar 2021 20:13:45

**US3862144**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	08 Mar 2021 22:36:15
	(b) (4)	

**US3862144**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '8 Mar 2021'	(b) (4) Thea Marie Cordero	08 Mar 2021 22:36:15
	(b) (4)	

**US3862144**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Thea Marie Cordero	08 Mar 2021 22:36:15
	(b) (4)	



**US3862144**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 10:02:10**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Thea Marie Cordero	08 Mar 2021 22:36:15
	(b) (4)	

**US3862144**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Thea Marie Cordero	08 Mar 2021 22:36:19
	(b) (4)	

**US3862144**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 10:02:10**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 14:40:36
User entered 'I'	System	08 Mar 2021 22:36:19

**US3862144**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	05 Apr 2021 15:52:53
	(b) (4)	

**US3862144**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
	(b) (4)	
User entered '05 Apr 2021'	Carrie Kibler (b) (4)	05 Apr 2021 15:52:53
	(b) (4)	

**US3862144**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
	(b) (4)	
User entered 'Clinic (Clinic)'	Carrie Kibler (b) (4)	05 Apr 2021 15:52:53
	(b) (4)	

**US3862144**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 10:02:10**

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	05 Apr 2021 15:52:53

**US3862144**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	05 Apr 2021 15:53:20
	(b) (4)	



**US3862144**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
	(b) (4)	
User entered '05 Apr 2021'	Carrie Kibler (b) (4)	05 Apr 2021 15:53:20
	(b) (4)	

**US3862144**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
	(b) (4)	
User entered '09:05'	Carrie Kibler (b) (4)	05 Apr 2021 15:53:20
	(b) (4)	

**US3862144**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '05 Apr 2021 09:05'	System	05 Apr 2021 15:53:20

**US3862144**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
	(b) (4)	
User entered '97.4' F	Carrie Kibler (b) (4)	05 Apr 2021 15:53:20
	(b) (4)	

**US3862144**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
	(b) (4)	
User entered 'Other (Other)'	Carrie Kibler (b) (4)	05 Apr 2021 15:53:20
	(b) (4)	

**US3862144**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
	(b) (4)	
User entered 'temporal'	Carrie Kibler (b) (4)	05 Apr 2021 15:53:20
	(b) (4)	

**US3862144**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
	(b) (4)	
User entered '81'	Carrie Kibler (b) (4)	05 Apr 2021 15:53:20
	(b) (4)	

**US3862144**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	05 Apr 2021 15:53:20



**US3862144**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
	(b) (4)	
User entered '15'	Carrie Kibler (b) (4)	05 Apr 2021 15:53:20
	(b) (4)	

**US3862144**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	05 Apr 2021 15:53:20

**US3862144**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
	(b) (4)	
User entered '119'	Carrie Kibler (b) (4)	05 Apr 2021 15:53:20
	(b) (4)	

**US3862144**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 15:53:20

**US3862144**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
	(b) (4)	
User entered '84'	Carrie Kibler (b) (4)	05 Apr 2021 15:53:20
	(b) (4)	

**US3862144**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 10:02:10**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	05 Apr 2021 15:53:20

**US3862144**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:02:10**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	05 Apr 2021 15:53:30
	(b) (4)	

**US3862144**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 10:02:10**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
	(b) (4)	
User entered '05 Apr 2021'	Carrie Kibler (b) (4)	05 Apr 2021 15:53:30
	(b) (4)	



**US3862144**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	05 Apr 2021 15:53:56
	(b) (4)	

**US3862144**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
	(b) (4)	
User entered '05 Apr 2021'	Carrie Kibler (b) (4)	05 Apr 2021 15:53:56
	(b) (4)	

**US3862144**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
	(b) (4)	
User entered '09:39'	Carrie Kibler (b) (4)	05 Apr 2021 15:53:56
	(b) (4)	

**US3862144**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 10:02:10**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '05 Apr 2021 09:39'	System	05 Apr 2021 15:53:56

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 10:02:10**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:04:48
DataPoint Verified.		14 Apr 2021 17:51:12
User signature succeeded.	Thea Marie Cordero	22 Mar 2021 15:17:36
User entered 'Yes (Y)'	(b) (4)	
	Carrie Kibler (b) (4)	05 Nov 2020 15:37:59
	(b) (4)	

US3862144

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:10

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Perirectal abscess, LLT: Perirectal abscess - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 15:44:25
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Nov 2020 15:44:25
	(b) (4)	
Data point term sent to Coder	System	05 Nov 2020 15:43:33
User entered 'perirectal abscess'	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	



**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered '4 Nov 2020'	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:42:37

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Carrie Kibler (b) (4)	07 Dec 2020 22:04:55
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered '2 Dec 2020' reason for change: New Information	Carrie Kibler (b) (4)	07 Dec 2020 22:04:55
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 15:42:37



**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	



**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	



**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered 'I'	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 10:02:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:54:54
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. answered with 'subject had colonoscopy and upon further investigation determined it was anal fistula.' (Site from DM).	Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:03:35
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 01:59:46
User entered 'I'	Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:42:37

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Carrie Kibler (b) (4)	07 Dec 2020 22:04:55
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	05 Nov 2020 15:42:37
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Nov 2020 15:42:37

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Nov 2020 15:42:37

US3862144

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:10

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 17:56:57
DataPoint Verified.		14 Apr 2021 17:53:47
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal conditions NEC, HLT: Gastrointestinal fistulae, PT: Anal fistula, LLT: Anal fistula - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	07 Dec 2020 22:06:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Dec 2020 22:06:52
Data point term sent to Coder	System	07 Dec 2020 22:05:59
User entered 'ANAL FISTULA'	Carrie Kibler (b) (4) (b) (4)	07 Dec 2020 22:05:38



**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 17:56:58
DataPoint Verified.		14 Apr 2021 17:53:48
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered 'Yes (Y)'	(b) (4)	
	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 17:57:03
DataPoint Verified.		14 Apr 2021 17:53:50
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered 'No (N)'	(b) (4)	
	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 17:57:00
DataPoint Verified.		14 Apr 2021 17:53:52
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered 'No (N)'	(b) (4)	
	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:53:54
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered '02 Dec 2020' reason for change: Data Entry Error	(b) (4)	05 Feb 2021 16:04:01
User entered '2 Dec 2020'	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 17:53:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered empty.	(b) (4)	07 Dec 2020 22:05:38
	Carrie Kibler (b) (4)	
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 22:05:38

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	05 Feb 2021 16:04:01
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered '03 Feb 2021' reason for change: Data Entry Error	Carrie Kibler (b) (4)	05 Feb 2021 16:04:01
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	



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**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Dec 2020 22:05:38

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered 'No (N)'	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	



**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	



**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

US3862144

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 10 Jun 2021 10:02:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Carrie Kibler (b) (4)	05 Feb 2021 16:04:01
	(b) (4)	
User entered '0'	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered 'I'	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Carrie Kibler (b) (4)	05 Feb 2021 16:04:01
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	07 Dec 2020 22:05:38
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Dec 2020 22:05:38



**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Dec 2020 22:05:38

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:31:30
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:56:48
User entered 'USA-US121-2021-mRNA-1273-P301000003'	System	01 Mar 2021 15:56:42
User entered 'New'	(b) (4), (b) (6)	01 Mar 2021 15:56:42

US3862144

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:10

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:31:32
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Gastrointestinal stenosis and obstruction NEC, PT: Intestinal obstruction, LLT: Partial bowel obstruction - version MedDRA\\23.0.	(b) (4) Corder Import (b) (4) (b) (4)	26 Mar 2021 23:03:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	26 Mar 2021 23:03:33
Data point term sent to Coder	System	26 Mar 2021 23:02:48
Coding entries removed.	Thea Marie Cordero (b) (4)	26 Mar 2021 23:01:51
User entered 'PARTIAL BOWEL OBSTRUCTION' reason for change: New Information	Thea Marie Cordero (b) (4)	26 Mar 2021 23:01:51
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Gastrointestinal stenosis and obstruction NEC, PT: Intestinal obstruction, LLT: Bowel obstruction - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Feb 2021 00:41:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Feb 2021 00:41:58
Data point term sent to Coder	System	27 Feb 2021 00:26:11
User entered 'bowel obstruction'	Sandra Francisco (b) (4) (b) (4)	27 Feb 2021 00:25:13

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:31:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered 'Yes (Y)'	(b) (4)	27 Feb 2021 00:25:13

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:31:38
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered 'No (N)'	(b) (4)	27 Feb 2021 00:25:13

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:31:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered 'No (N)'	(b) (4)	27 Feb 2021 00:25:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'As per Medical records dated 21Feb,pg7 of 39, narrative mentions that symptoms started two days prior to hospitalization. Please verify and update the start date as needed.' answered with 'DATA CORRECTED IN SOURCE DOCUMENT AND EDC' (Site from CRA). Signature has been broken.	Thea Marie Cordero (b) (4)	15 Apr 2021 19:39:13
	Thea Marie Cordero (b) (4)	15 Apr 2021 19:38:53
User entered '19 Feb 2021' reason for change: New Information	Thea Marie Cordero (b) (4)	15 Apr 2021 19:38:53
User opened query 'As per Medical records dated 21Feb,pg7 of 39, narrative mentions that symptoms started two days prior to hospitalization. Please verify and update the start date as needed.' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:32:15
	(b) (4), (b) (6)	14 Apr 2021 20:14:33
DataPoint Verified.		14 Apr 2021 18:31:44
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:23:16
User entered '21 Feb 2021'	Sandra Francisco (b) (4) (b) (4)	27 Feb 2021 00:25:13

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:31:46
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered empty.	(b) (4)	27 Feb 2021 00:25:13



**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Feb 2021 00:25:13

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:31:48
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered 'No (N)'	(b) (4)	27 Feb 2021 00:25:13
	Sandra Francisco (b) (4)	
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:31:57
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered '24 Feb 2021'	(b) (4)	
	Sandra Francisco (b) (4)	27 Feb 2021 00:25:13
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:32:01
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered empty.	(b) (4)	27 Feb 2021 00:25:13

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Feb 2021 00:25:13

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:32:05
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4)	
	Sandra Francisco (b) (4)	27 Feb 2021 00:25:13
	(b) (4)	

US3862144

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:10

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:32:16
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
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 Feb 2021 00:25:33
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 Feb 2021 00:25:13
User entered 'Yes (Y)'	Sandra Francisco (b) (4)	27 Feb 2021 00:25:13

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:32:19
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered '0'	(b) (4)	
	Sandra Francisco (b) (4)	27 Feb 2021 00:25:13
	(b) (4)	



**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:32:21
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered '0'	Sandra Francisco (b) (4)	27 Feb 2021 00:25:13

US3862144

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:10

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Thank you for your recent response. 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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 14:17:26
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:23:16
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		27 Feb 2021 00:26:38
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		27 Feb 2021 00:26:38
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		27 Feb 2021 00:25:33
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).		27 Feb 2021 00:25:33
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	27 Feb 2021 00:25:33
User entered '1' reason for change: Data Entry Error	Sandra Francisco (b) (4)	27 Feb 2021 00:25:33
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	27 Feb 2021 00:25:13

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User entered '0'	Sandra Francisco (b) (4) (b) (4)	27 Feb 2021 00:25:13

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:32:26
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
	(b) (4)	
User entered '21 Feb 2021' reason for change: Data Entry Error	Sandra Francisco	(b) (4) 27 Feb 2021 00:26:38
	(b) (4)	
User entered empty.	Sandra Francisco	(b) (4) 27 Feb 2021 00:25:13
	(b) (4)	

US3862144

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:10

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:32:29
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:28:35
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are 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 22:24:25
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Mar 2021 20:40:15
User entered '24 Feb 2021' reason for change: Data Entry Error	Sandra Francisco (b) (4) (b) (4)	27 Feb 2021 00:26:38
User entered empty.	Sandra Francisco (b) (4) (b) (4)	27 Feb 2021 00:25:13

US3862144

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:10

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM Re-Query: Site response noted. Please update when available and then route back to DM. Thank you. ' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 21:23:56
Query 'Per CDM Re-Query: Site response noted. Please update when available and then route back to DM. Thank you. ' answered with 'No ICU admission as reflected in medical records' (Site from DM).	Thea Marie Cordero (b) (4)	23 Apr 2021 17:02:36
Signature has been broken.	Thea Marie Cordero (b) (4)	23 Apr 2021 17:00:19
User entered 'No (N)' reason for change: New Information	Thea Marie Cordero (b) (4)	23 Apr 2021 17:00:19
User closed query 'Per CDM Re-Query: Site response noted. Please update when available and then route back to DM. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 05:50:28
User opened query 'Per CDM Re-Query: Site response noted. Please update when available and then route back to DM. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 05:50:26
Query 'Per CDM Re-Query: Site response noted. Please update when available and then route back to DM. Thank you.' answered with 'pending medical records ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 20:02:26
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 13:10:36
User opened query 'Per CDM Re-Query: Site response noted. Please update when available and then route back to DM. Thank you.' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 13:10:35
User signature succeeded.	Thea Marie Cordero (b) (4)	29 Mar 2021 14:23:16
Query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered with 'PENDING MEDICAL RECORDS.' (Site from System).	Carrie Kibler (b) (4) (b) (4)	24 Mar 2021 22:24:28
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	27 Feb 2021 00:25:13
User entered 'Unknown (UNK)'	Sandra Francisco (b) (4) (b) (4)	27 Feb 2021 00:25:13

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:33:36
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered empty.	(b) (4)	27 Feb 2021 00:25:13

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:33:14
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered '0'	(b) (4)	27 Feb 2021 00:25:13



**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:33:05
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered '0'	(b) (4)	27 Feb 2021 00:25:13

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:33:09
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered '0'	(b) (4)	27 Feb 2021 00:25:13

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:33:11
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Sandra Francisco (b) (4)	27 Feb 2021 00:25:13
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:33:40
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered 'Not Related (NOT RELATED)'	(b) (4)	
	Sandra Francisco (b) (4)	27 Feb 2021 00:25:13
	(b) (4)	

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:33:42
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered 'None (NONE)'	(b) (4)	
	Sandra Francisco (b) (4)	27 Feb 2021 00:25:13
	(b) (4)	

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:35:37
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered '0'	Sandra Francisco (b) (4)	27 Feb 2021 00:25:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per CDM Re-Query: Site response noted. Please update when available and then route back to DM. Thank you. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 21:24:00
User closed query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. If information will not be available, please state so. Otherwise, please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 18:33:53
Query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. If information will not be available, please state so. Otherwise, please leave query open until information is available. ' answered with 'ENTERED IN SOURCE DOCUMENT AND EDC' (Site from Safety).	Thea Marie Cordero (b) (4)	13 Apr 2021 22:05:12
User opened query 'PV Query: Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. If information will not be available, please state so. Otherwise, please leave query open until information is available. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 12:54:57
Query 'Per CDM Re-Query: Site response noted. Please update when available and then route back to DM. Thank you. ' answered with 'pending medical records ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 20:03:55
User opened query 'Per CDM Re-Query: Site response noted. Please update when available and then route back to DM. Thank you. ' (Site from DM)	(b) (4), (b) (6)	01 Apr 2021 13:10:48

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:10

Concomitant Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication and Concomitant Procedure, however there is no Concomitant Medication and Concomitant Procedure recorded that match this AE during this timeframe. Please review and add a Con Medication or Con Procedure as appropriate or update action taken.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	01 Apr 2021 13:10:48
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	Thea Marie Cordero (b) (4) (b) (4), (b) (6)	29 Mar 2021 14:23:16 25 Mar 2021 14:28:39
Query 'Per DM CLR: Other Action Taken = Concomitant Medication and Concomitant Procedure, however there is no Concomitant Medication and Concomitant Procedure recorded that match this AE during this timeframe. Please review and add a Con Medication or Con Procedure as appropriate or update action taken.' answered with 'PENDING MEDICAL RECORDS.' (Site from DM).	Carrie Kibler (b) (4)	24 Mar 2021 22:24:35
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'PENDING MEDICAL RECORDS.' (Site from Safety).	Carrie Kibler (b) (4)	24 Mar 2021 22:24:32
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication and Concomitant Procedure, however there is no Concomitant Medication and Concomitant Procedure recorded that match this AE during this timeframe. Please review and add a Con Medication or Con Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 06:01:40



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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:10

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Mar 2021 20:39:26
User entered 'I'	Sandra Francisco (b) (4)	27 Feb 2021 00:25:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:10

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:35:25
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	25 Mar 2021 14:28:42
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'PENDING MEDICAL RECORDS.' (Site from Safety).	Carrie Kibler (b) (4) (b) (4)	24 Mar 2021 22:24:38
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	06 Mar 2021 20:39:49
User entered 'I'	Sandra Francisco (b) (4) (b) (4)	27 Feb 2021 00:25:13

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:34:25
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Sandra Francisco (b) (4) (b) (4)	27 Feb 2021 00:25:13

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:34:27
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
User entered empty.	(b) (4)	27 Feb 2021 00:25:13

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:10

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:35:04
User closed query 'PV Query: Please provide dates and normal reference ranges for labs. If unknown, please indicate so. ' (Site from Safety).		14 Apr 2021 15:25:42
User closed query 'PV Query: Please provide results for EKG, CT scan, and chest x-ray. ' (Site from Safety).		14 Apr 2021 15:25:39
Query 'PV Query: Please provide results for EKG, CT scan, and chest x-ray. ' answered with 'EKG: SINUS RHYTHM, CT SCAN ABDOMEN AND PELVIS:DILATATION OF PROXIMAL JEJUNUM WITH MILD ADJACENT MESENTERIC STRANDING SUSPICIOUS FOR PARTIAL BOWEL OBSTRUCTION NO CHEST XRAY DONE. ABDOMINAL XRAY: FOR NGT PLACEMENT CONFIRMATION' (Site from Safety).	Thea Marie Cordero (b) (4)	13 Apr 2021 22:27:49
Query 'PV Query: Please provide dates and normal reference ranges for labs. If unknown, please indicate so. ' answered with 'THESE ARE THE ONLY SIGNIFICANT LAB RESULTS :WBC 11 mc/L, NEUTROPHIL 70.8 mc/L, BUN 28 mg/dL' (Site from Safety).	Thea Marie Cordero (b) (4)	13 Apr 2021 22:10:47
Signature has been broken.	Thea Marie Cordero (b) (4)	13 Apr 2021 22:01:17
User entered 'SUBJECT HOSPITALIZED FROM 21 FEB 2021- 24 FEB 2021, DIAGNOSIS PARTIAL BOWEL OBSTRUCTION. MANAGED CONSERVATIVELY WITH PAIN MEDICAITONS, ANTI-EMETICS AND WAS KEPT NPO.' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	13 Apr 2021 22:01:17
User opened query 'PV Query: Thank you for your recent response. 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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 12:55:07

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide dates and normal reference ranges for labs. If unknown, please indicate so. ' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 12:54:42
User opened query 'PV Query: Please provide results for EKG, CT scan, and chest x-ray. ' (Site from Safety).		13 Apr 2021 12:54:34
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).		07 Apr 2021 17:14:35
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. If information will not be available, please state so. Otherwise, please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 17:14:33
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. If information will not be available, please state so. Otherwise, please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 17:14:29
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. If information will not be available, please state so. Otherwise, please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 17:14:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 10 Jun 2021 10:02:10

[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. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. If information will not be available, please state so. Otherwise, please leave query open until information is available.'	Thea Marie Cordero (b) (4)	06 Apr 2021 00:24:01
answered with 'WBC 11 mc/L, NEUTROPHIL 70.8 mc/L, BUN 28 mg/dL' (Site from Safety). 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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.'	Thea Marie Cordero (b) (4)	06 Apr 2021 00:18:43
answered with 'WILL BE DONE AFTER REDACTION' (Site from Safety). Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. If information will not be available, please state so. Otherwise, please leave query open until information is available.'	Thea Marie Cordero (b) (4)	06 Apr 2021 00:18:30
answered with 'SEE CONCOMITANT MEDICATION LIST. PROCEDURES: EKG, CT SCAN ABDOMEN, PELVIS,NGT PLACEMENT, CHEST XRAY' (Site from Safety). 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. If information will not be available, please state so. Otherwise, please leave query open until information is available.'	Thea Marie Cordero (b) (4)	06 Apr 2021 00:17:06
answered with 'COVID 19 TESTING NOT PROVIDED FROM AVAILABLE MEDICAL RECORDS' (Site from Safety).		

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Folder: Adverse Events

Form: Adverse Events (3)

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[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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 16:34:06
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response. If information will not be available, please state so. Otherwise, please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 16:33:27
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so. If information will not be available, please state so. Otherwise, please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 16:33:17
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. If information will not be available, please state so. Otherwise, please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	05 Apr 2021 16:33:00
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 15:57:49



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Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 15:57:47
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 15:57:44
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 15:57:41
User signature succeeded.	Thea Marie Cordero	29 Mar 2021 14:23:16
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'INFORMATION UNAVAILABLE. AWAITING MEDICAL RECORDS' (Site from Safety).	(b) (4)	
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'INFORMATION UNAVAILABLE. AWAITING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero	26 Mar 2021 23:09:35
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'INFORMATION UNAVAILABLE. AWAITING MEDICAL RECORDS' (Site from Safety).	(b) (4)	
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'INFORMATION UNAVAILABLE. AWAITING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero	26 Mar 2021 23:09:30
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'INFORMATION UNAVAILABLE. AWAITING MEDICAL RECORDS' (Site from Safety).	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'INFORMATION UNAVAILABLE. AWAITING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	26 Mar 2021 23:09:22
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 'INFORMATION UNAVAILABLE. AWAITING MEDICAL RECORDS' (Site from Safety).	Thea Marie Cordero (b) (4)	26 Mar 2021 23:08:45
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 16:59:06
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 16:59:02
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 16:58:56

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Folder: Adverse Events

Form: Adverse Events (3)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Mar 2021 16:58:52
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 14:28:45
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 22:24:41
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)	06 Mar 2021 20:39:12
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	27 Feb 2021 00:27:57
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	27 Feb 2021 00:27:57
User entered 'Details of AE to be provided once medical records are available.' reason for change: Data Entry Error	Sandra Francisco (b) (4) (b) (4)	27 Feb 2021 00:27:57
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	27 Feb 2021 00:25:13
User entered empty.	Sandra Francisco (b) (4) (b) (4)	27 Feb 2021 00:25:13

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Feb 2021 00:25:13

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**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Feb 2021 00:25:13

**US3862144**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	27 Feb 2021 00:25:13

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 10:02:10

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:04:48
DataPoint Verified.		14 Apr 2021 18:37:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:21:49

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 10:02:10

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:23:23
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 19:24:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	11 Sep 2020 19:24:42
Data point term sent to Coder	System	11 Sep 2020 19:23:40
User entered 'Amlodipine'	Trent Davis (b) (4)	11 Sep 2020 19:23:02
	(b) (4)	



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:23:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:23:02

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:23:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'High Blood PResure'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:23:02

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:23:28
User signature succeeded.	Hana El Sahly (b) (4)	09 Apr 2021 18:36:06
Signature has been broken.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 23:31:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '5'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:23:02

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:23:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'mg (mg)'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:23:02

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:23:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:23:02

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
User entered 'once daily (QD)'	Trent Davis (b) (4)	11 Sep 2020 19:23:02
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:23:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:23:02

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:23:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Oral (ORAL)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:23:02



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:23:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:23:02

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:24:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'un UNK 2019'	Trent Davis (b) (4)	11 Sep 2020 19:23:02

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:24:16
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '0'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:23:02

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:24:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:23:02

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:24:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:23:02

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:24:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:23:02

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 19:23:02

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 19:23:02



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 19:23:02

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:10

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:25:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: LOW-CEILING DIURETICS, THIAZIDES, ATC: THIAZIDES, PLAIN, PRODUCT: HYDROCHLOROTHIAZIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 19:25:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 19:25:44
Data point term sent to Coder	System	11 Sep 2020 19:24:46
User entered 'Hydrochlorothiazide'	Trent Davis (b) (4)	11 Sep 2020 19:24:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:25:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:24:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:25:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'High Blood Pressure'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:24:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:25:10
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '25'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:24:33

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:10

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:25:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'mg (mg)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:24:33

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 10:02:10

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:25:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:24:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
User entered 'once daily (QD)'	Trent Davis (b) (4)	11 Sep 2020 19:24:33
	(b) (4)	



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:02:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:25:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:24:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:25:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Oral (ORAL)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:24:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:02:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:25:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:24:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:25:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'un UNK 2019'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:24:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:25:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:24:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:25:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:24:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:02:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:25:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:24:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:25:34
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:24:33



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 19:24:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 19:24:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 19:24:33

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:10

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:27:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User closed query 'Per DM CLR: Please verify if this is a combination medication and if so, please update the medication name field to reflect both generic components/trade name as there are two doses specified in the dose field. Please update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Nov 2020 13:40:27
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)	10 Nov 2020 21:30:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 21:30:40
Data point term sent to Coder	System	09 Nov 2020 18:09:52
Query 'Per DM CLR: Please verify if this is a combination medication and if so, please update the medication name field to reflect both generic components/trade name as there are two doses specified in the dose field. Please update as appropriate. ' answered with 'Updated' (Site from DM).	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 18:09:48
Coding entries removed.	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 18:09:42
User entered 'HYDROCODONE Acetaminophen' reason for change: Data Entry Error	Shetel Anassi (b) (4) (b) (4)	09 Nov 2020 18:09:42
User opened query 'Per DM CLR: Please verify if this is a combination medication and if so, please update the medication name field to reflect both generic components/trade name as there are two doses specified in the dose field. Please update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 10:42:05

PRODUCTION RELEASE (v12.003  
EAB) (1725)

2003 of 2430

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 10:02:10

[Name of Medication](#)

Audit	User	Time (GMT)
Query 'v' canceled (Site from DM).	(b) (4), (b) (6)	08 Nov 2020 10:42:01
User opened query 'v' (Site from DM).		08 Nov 2020 10:41:58
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 19:27:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Sep 2020 19:27:40
Data point term sent to Coder	System	11 Sep 2020 19:26:50
User entered 'Hydrocodone'	Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:26:24

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:27:48
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:26:24

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:27:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Chronic Back PAin'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:26:24

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:27:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '10-325'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:26:24



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:29:11
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'mg (mg)'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:26:24

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:10**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:29:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:26:24

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:29:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'four times daily (QID)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:26:24

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:29:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:26:24

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:29:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Oral (ORAL)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:26:24

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:29:34
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:26:24

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:29:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'un UNK 2010'	Trent Davis (b) (4)	11 Sep 2020 19:26:24

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:29:37
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '0'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:26:24



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:29:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:26:24

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:29:43
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:26:24

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:29:44
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:26:24

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '4'	System	11 Sep 2020 19:26:24

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 19:26:24

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 19:26:24

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:10

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:30:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Oct 2020 23:44:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Oct 2020 23:44:33
Data point term sent to Coder Coding entries removed.	System	10 Oct 2020 23:43:15
	Coni Cheesman (b) (4)	10 Oct 2020 23:42:51
User entered 'PREGABALIN' reason for change: Data Entry Error	Coni Cheesman (b) (4)	10 Oct 2020 23:42:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: PREGABALIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 04:35:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Sep 2020 04:35:47
Data point term sent to Coder	System	11 Sep 2020 19:27:54
User entered 'Pregablin'	Trent Davis (b) (4)	11 Sep 2020 19:27:27

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:30:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:27:27



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:30:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Peripheral Neuropathy'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:27:27

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:30:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '300'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:27:27

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:30:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'mg (mg)'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:27:27

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:30:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:27:27

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:30:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'twice daily (BID)'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:27:27

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:30:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:27:27

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:30:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Oral (ORAL)'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:27:27

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:30:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:27:27



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:30:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'un UNK 2018'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:27:27

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:30:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '0'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:27:27

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:30:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:27:27

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:30:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:27:27

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 10:02:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:30:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:27:27

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	11 Sep 2020 19:27:27

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 19:27:27

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 19:27:27



US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 10:02:10

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
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: EMTRICITABINE;RILPIVIRINE HYDROCHLORIDE;TENOFVIR ALAFENAMIDE FUMARATE, PRODUCTSYNONYM: ODEFSEY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 19:30:36
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 19:30:36
Data point term sent to Coder	System	11 Sep 2020 19:30:00
User entered 'Odefsey'	Trent Davis (b) (4)	11 Sep 2020 19:29:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:29:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'human immunodeficiency virus'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:29:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'I'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:29:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'tablet (TABLET)'	Trent Davis (b) (4)	11 Sep 2020 19:29:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:10**

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:29:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'once daily (QD)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:29:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:29:33



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Oral (ORAL)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:29:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:29:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'un UNK 2019'	Trent Davis (b) (4)	11 Sep 2020 19:29:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '0'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:29:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:29:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:29:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:29:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 19:29:33



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 19:29:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 19:29:33

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:10

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: VITAMIN B12 AND FOLIC ACID, ATC: VITAMIN B12 (CYANOCOBALAMIN AND ANALOGUES), PRODUCT: VITAMIN B12 NOS, PRODUCTSYNONYM: VITAMIN B12 [VITAMIN B12 NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Sep 2020 19:38:41
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	11 Sep 2020 19:38:41
Data point term sent to Coder	System	11 Sep 2020 19:38:17
Data point term sent to Coder	System	11 Sep 2020 19:37:12
User entered 'Vitamin B12'	Trent Davis (b) (4)	11 Sep 2020 19:36:51
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:36:51

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:10**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'B12 Deficiency' reason for change:	(b) (4)	
Data Entry Error	Trent Davis (b) (4)	11 Sep 2020 19:37:27
User entered 'Low B12'	(b) (4)	
	Trent Davis (b) (4)	11 Sep 2020 19:36:51
	(b) (4)	

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:10

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	03 Feb 2021 19:43:34
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'PLEASE REFER TO DOSE UNIT: THIS IS THE STANDARD DOSE: 1ug= 1 microgram' (Site from DM).	Thea Marie Cordero (b) (4)	02 Feb 2021 14:55:09
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 14:45:21
User entered 'I'	Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:36:51

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	05 Nov 2020 15:35:06
User entered 'Other (OTHER)'	Carrie Kibler (b) (4)	11 Sep 2020 19:36:51
	(b) (4)	

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:10

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty; reason for change Data Entry Error	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:35:06
User entered 'mcg'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:36:51



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:10**

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 19:43:05
DataPoint Verified.		14 Apr 2021 19:42:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'once daily (QD)'	(b) (4) Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:36:51

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:36:51

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:10**

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Oral (ORAL)'	Trent Davis (b) (4)	11 Sep 2020 19:36:51

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:36:51

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'un UNK 2018'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:36:51

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '0'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:36:51

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:10**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:36:51

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:36:51



US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 10:02:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:42:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) Trent Davis (b) (4)	11 Sep 2020 19:36:51

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 19:36:51

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	11 Sep 2020 19:36:51

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	11 Sep 2020 19:36:51

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:54
DataPoint Verified.		14 Apr 2021 19:44:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
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)	05 Nov 2020 15:37:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	05 Nov 2020 15:36:18
User entered 'influenza vaccine'	Carrie Kibler (b) (4)	05 Nov 2020 15:35:40
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Carrie Kibler (b) (4)	05 Nov 2020 15:34:33
	(b) (4)	
	Trent Davis (b) (4)	11 Sep 2020 19:37:57
	(b) (4)	

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:54
DataPoint Verified.		14 Apr 2021 19:44:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:35:40
DataPoint activated with code reason code Data required.	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:34:33
DataPoint inactivated with code reason code Data not required.	Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:37:57

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:54
DataPoint Verified.		14 Apr 2021 19:44:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'influenza prevention'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:35:40
DataPoint activated with code reason code Data required.	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:34:33
DataPoint inactivated with code reason code Data not required.	Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:37:57

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:54
DataPoint Verified.		14 Apr 2021 19:44:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '0.5'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:35:40
DataPoint activated with code reason code Data required.	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:34:33
DataPoint inactivated with code reason code Data not required.	Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:37:57



US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:54
DataPoint Verified.		14 Apr 2021 19:44:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'mL (mL)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:35:40
DataPoint activated with code reason code Data required.	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:34:33
DataPoint inactivated with code reason code Data not required.	Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:37:57

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:54
DataPoint Verified.		14 Apr 2021 19:44:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:35:40
DataPoint activated with code reason code Data required.	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:34:33
DataPoint inactivated with code reason code Data not required.	Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:37:57

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:54
DataPoint Verified.		14 Apr 2021 19:44:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'once (ONCE)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:35:40
DataPoint activated with code reason code Data required.	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:34:33
DataPoint inactivated with code reason code Data not required.	Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:37:57

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:54
DataPoint Verified.		14 Apr 2021 19:44:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:35:40
DataPoint activated with code reason code Data required.	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:34:33
DataPoint inactivated with code reason code Data not required.	Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:37:57

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:54
DataPoint Verified.		14 Apr 2021 19:44:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	Carrie Kibler (b) (4)	05 Nov 2020 15:35:40
	(b) (4)	
DataPoint activated with code reason code Data required.	Carrie Kibler (b) (4)	05 Nov 2020 15:34:33
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Trent Davis (b) (4)	11 Sep 2020 19:37:57
	(b) (4)	

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:54
DataPoint Verified.		14 Apr 2021 19:44:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:35:40
DataPoint activated with code reason code Data required.	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:34:33
DataPoint inactivated with code reason code Data not required.	Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:37:57

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:54
DataPoint Verified.		14 Apr 2021 19:44:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '23 Oct 2020'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:35:40
DataPoint activated with code reason code Data required.	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:34:33
DataPoint inactivated with code reason code Data not required.	Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:37:57

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:10

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:54
DataPoint Verified.		14 Apr 2021 19:44:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '0'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:35:40
DataPoint activated with code reason code Data required.	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:34:33
DataPoint inactivated with code reason code Data not required.	Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:37:57



US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:54
DataPoint Verified.		14 Apr 2021 19:44:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:35:40
DataPoint activated with code reason code Data required.	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:34:33
DataPoint inactivated with code reason code Data not required.	Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:37:57

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:54
DataPoint Verified.		14 Apr 2021 19:44:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '23 Oct 2020'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:35:40
DataPoint activated with code reason code Data required.	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:34:33
DataPoint inactivated with code reason code Data not required.	Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:37:57

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:54
DataPoint Verified.		14 Apr 2021 19:44:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:35:40
DataPoint activated with code reason code Data required.	(b) (4) Carrie Kibler (b) (4)	05 Nov 2020 15:34:33
DataPoint inactivated with code reason code Data not required.	Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:37:57

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:10

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:54
User entered empty.	System	05 Nov 2020 15:35:40
DataPoint activated with code reason code Data required.	Carrie Kibler (b) (4)	05 Nov 2020 15:34:33
DataPoint inactivated with code reason code Data not required.	Trent Davis (b) (4)	11 Sep 2020 19:37:57

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:10

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:54
User entered empty.	System	05 Nov 2020 15:35:40
DataPoint activated with code reason code Data required.	Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:34:33
DataPoint inactivated with code reason code Data not required.	Trent Davis (b) (4) (b) (4)	11 Sep 2020 19:37:57

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 10:02:10

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:54
User entered empty.	System	05 Nov 2020 15:35:40
DataPoint activated with code reason code Data required.	Carrie Kibler (b) (4)	05 Nov 2020 15:34:33
DataPoint inactivated with code reason code Data not required.	Trent Davis (b) (4)	11 Sep 2020 19:37:57

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
DataPoint Verified.		14 Apr 2021 19:47:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - 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)	05 Nov 2020 16:46:26
Data point term sent to Coder	(b) (4)	
User entered 'doxycycline'	System	05 Nov 2020 15:37:18
	Carrie Kibler (b) (4)	05 Nov 2020 15:36:31
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
DataPoint Verified.		14 Apr 2021 19:47:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:36:31



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
DataPoint Verified.		14 Apr 2021 19:47:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'perirectal abscess'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:36:31

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
DataPoint Verified.		14 Apr 2021 19:47:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '100'	(b) (4)	
	Carrie Kibler (b) (4)	05 Nov 2020 15:36:31
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
DataPoint Verified.		14 Apr 2021 19:47:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'mg (mg)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:36:31

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
DataPoint Verified.		14 Apr 2021 19:47:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	05 Nov 2020 15:36:31
	(b) (4)	

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
DataPoint Verified.		14 Apr 2021 19:47:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'twice daily (BID)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:36:31

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
DataPoint Verified.		14 Apr 2021 19:47:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4)	05 Nov 2020 15:36:31
	Carrie Kibler (b) (4)	
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
DataPoint Verified.		14 Apr 2021 19:47:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Oral (ORAL)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:36:31

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
DataPoint Verified.		14 Apr 2021 19:47:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	05 Nov 2020 15:36:31
	(b) (4)	



US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 10:02:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
DataPoint Verified.		14 Apr 2021 19:47:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
User entered '6 Nov 2020' reason for change: Data Entry Error	Carrie Kibler (b) (4)	02 Dec 2020 22:39:42
	(b) (4)	
User entered '5 Nov 2020'	Carrie Kibler (b) (4)	05 Nov 2020 15:36:31
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
DataPoint Verified.		14 Apr 2021 19:47:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:36:31

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
DataPoint Verified.		14 Apr 2021 19:47:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	02 Dec 2020 22:39:42
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	05 Nov 2020 15:36:31
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
DataPoint Verified.		14 Apr 2021 19:47:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
User entered '15 Nov 2020' reason for change: Data Entry Error	Carrie Kibler (b) (4)	02 Dec 2020 22:39:42
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	05 Nov 2020 15:36:31
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
DataPoint Verified.		14 Apr 2021 19:47:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:36:31

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
User entered '2'	System	05 Nov 2020 15:36:31

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
User entered '1'	System	05 Nov 2020 15:36:31

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:56:58
User entered '804 (804)'	System	05 Nov 2020 15:36:31



US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:01
DataPoint Verified.		14 Apr 2021 19:47:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	05 Nov 2020 16:15:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 16:15:21
Data point term sent to Coder	System	05 Nov 2020 15:37:21
User entered 'ciprofloxacin'	Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:36:55

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:01
DataPoint Verified.		14 Apr 2021 19:47:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4)	
	Carrie Kibler (b) (4)	05 Nov 2020 15:36:55
	(b) (4)	

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:01
DataPoint Verified.		14 Apr 2021 19:47:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'perirectal abscess'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:36:55

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:01
DataPoint Verified.		14 Apr 2021 19:47:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '500'	(b) (4)	
	Carrie Kibler (b) (4)	05 Nov 2020 15:36:55
	(b) (4)	

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:01
DataPoint Verified.		14 Apr 2021 19:47:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'mg (mg)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:36:55

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:10**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:01
DataPoint Verified.		14 Apr 2021 19:47:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	05 Nov 2020 15:36:55
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:01
DataPoint Verified.		14 Apr 2021 19:47:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'twice daily (BID)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:36:55

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:01
DataPoint Verified.		14 Apr 2021 19:47:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	05 Nov 2020 15:36:55
	(b) (4)	



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:01
DataPoint Verified.		14 Apr 2021 19:47:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Oral (ORAL)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:36:55

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:01
DataPoint Verified.		14 Apr 2021 19:47:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	05 Nov 2020 15:36:55
	(b) (4)	

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 10:02:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:01
DataPoint Verified.		14 Apr 2021 19:47:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
User entered '6 Nov 2020' reason for change: Data Entry Error	Carrie Kibler (b) (4)	02 Dec 2020 22:40:40
	(b) (4)	
User entered '5 Nov 2020'	Carrie Kibler (b) (4)	05 Nov 2020 15:36:55
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:01
DataPoint Verified.		14 Apr 2021 19:47:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:36:55

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:01
DataPoint Verified.		14 Apr 2021 19:47:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Carrie Kibler (b) (4)	02 Dec 2020 22:40:40
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	05 Nov 2020 15:36:55
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:01
DataPoint Verified.		14 Apr 2021 19:47:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
User entered '15 Nov 2020' reason for change: Data Entry Error	Carrie Kibler (b) (4)	02 Dec 2020 22:40:40
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	05 Nov 2020 15:36:55
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:01
DataPoint Verified.		14 Apr 2021 19:47:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4)	
	Carrie Kibler (b) (4)	05 Nov 2020 15:36:55
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:01
User entered '2'	System	05 Nov 2020 15:36:55



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:01
User entered '1'	System	05 Nov 2020 15:36:55

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:01
User entered '804 (804)'	System	05 Nov 2020 15:36:55

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:06
DataPoint Verified.		14 Apr 2021 19:47:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:36:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	05 Nov 2020 16:36:28
Data point term sent to Coder	System	05 Nov 2020 15:38:27
User entered 'metronidazole'	Carrie Kibler (b) (4)	05 Nov 2020 15:37:36

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:06
DataPoint Verified.		14 Apr 2021 19:47:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4)	
	Carrie Kibler (b) (4)	05 Nov 2020 15:37:36
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:06
DataPoint Verified.		14 Apr 2021 19:47:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'perirectal abscess'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:37:36

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:06
DataPoint Verified.		14 Apr 2021 19:47:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '500'	(b) (4)	
	Carrie Kibler (b) (4)	05 Nov 2020 15:37:36
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:06
DataPoint Verified.		14 Apr 2021 19:47:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'mg (mg)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:37:36

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:10**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:06
DataPoint Verified.		14 Apr 2021 19:47:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	05 Nov 2020 15:37:36
	(b) (4)	



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:06
DataPoint Verified.		14 Apr 2021 19:47:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'three times daily (TID)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:37:36

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:06
DataPoint Verified.		14 Apr 2021 19:47:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	05 Nov 2020 15:37:36
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:06
DataPoint Verified.		14 Apr 2021 19:47:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Oral (ORAL)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:37:36

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:06
DataPoint Verified.		14 Apr 2021 19:47:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	05 Nov 2020 15:37:36
	(b) (4)	

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 10:02:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:06
DataPoint Verified.		14 Apr 2021 19:47:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
User entered '6 Nov 2020' reason for change: New Information	Carrie Kibler (b) (4)	02 Dec 2020 22:40:58
	(b) (4)	
User entered '5 Nov 2020'	Carrie Kibler (b) (4)	05 Nov 2020 15:37:36
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:06
DataPoint Verified.		14 Apr 2021 19:47:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:37:36

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:06
DataPoint Verified.		14 Apr 2021 19:47:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Carrie Kibler (b) (4)	02 Dec 2020 22:40:58
	(b) (4)	
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	05 Nov 2020 15:37:36
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:06
DataPoint Verified.		14 Apr 2021 19:47:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
User entered '15 Nov 2020' reason for change: New Information	Carrie Kibler (b) (4)	02 Dec 2020 22:40:58
	(b) (4)	
User entered empty.	Carrie Kibler (b) (4)	05 Nov 2020 15:37:36
	(b) (4)	



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:06
DataPoint Verified.		14 Apr 2021 19:47:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Nov 2020 15:37:36

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:06
User entered '3'	System	05 Nov 2020 15:37:36

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:06
User entered '1'	System	05 Nov 2020 15:37:36

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:06
User entered '804 (804)'	System	05 Nov 2020 15:37:36

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:08
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) (b) (4)	16 Apr 2021 01:04:04
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 01:04:04
Data point term sent to Coder	System	15 Apr 2021 20:18:01
Coding entries removed.	(b) (4), (b) (6)	15 Apr 2021 20:17:11
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:50:12
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:27:27
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) (b) (4)	06 Feb 2021 19:42:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Feb 2021 19:42:54
Data point term sent to Coder	System	05 Feb 2021 16:24:05
User entered 'Ibuprofen'	Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:07

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:08
DataPoint Verified.		19 Apr 2021 22:00:38
User closed query 'As per source it is "Yes". Please verify and update as needed.' (Site from CRA).		19 Apr 2021 21:59:53
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
Query 'As per source it is "Yes". Please verify and update as needed.' answered with 'data correction done in edc ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:18:15
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 20:17:11
User entered 'Yes (Y)' reason for change: Data Entry Error		15 Apr 2021 20:17:11
User opened query 'As per source it is "Yes". Please verify and update as needed.' (Site from CRA).		14 Apr 2021 19:52:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:07

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:08
DataPoint Verified.		19 Apr 2021 22:00:48
User closed query 'As per source, it is for rectal pain for Seton Placement. Please verify and update as needed.' (Site from CRA).		19 Apr 2021 22:00:07
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
Query 'As per source, it is for rectal pain for Seton Placement. Please verify and update as needed.' answered with 'data correction done in edc ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:18:05
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 20:17:11
User entered 'prophylaxes for rectal pain for seton placement' reason for change: Data Entry Error		15 Apr 2021 20:17:11
User opened query 'As per source, it is for rectal pain for Seton Placement. Please verify and update as needed.' (Site from CRA).		14 Apr 2021 19:54:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Fistulotomy'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:07

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 10:02:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:08
DataPoint Verified.		19 Apr 2021 22:01:02
User closed query 'As per source it is 800 mg. Please verify and update.' (Site from CRA).		19 Apr 2021 22:00:19
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
Query 'As per source it is 800 mg. Please verify and update.' answered with 'data updated in edc ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:17:31
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 20:17:11
User entered '800' reason for change: Data Entry Error		15 Apr 2021 20:17:11
User opened query 'As per source it is 800 mg. Please verify and update.' (Site from CRA).		14 Apr 2021 19:54:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '600'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:07



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:08
DataPoint Verified.		14 Apr 2021 19:50:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'mg (mg)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:07

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:02:10**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:08
DataPoint Verified.		14 Apr 2021 19:50:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	05 Feb 2021 16:23:07
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:02:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:08
DataPoint Verified.		14 Apr 2021 19:50:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'other (OTHER)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:07

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:02:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:08
DataPoint Verified.		14 Apr 2021 19:50:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Every 8 hours PRN'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:07

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:02:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:08
DataPoint Verified.		14 Apr 2021 19:51:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Oral (ORAL)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:07

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:02:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:08
DataPoint Verified.		14 Apr 2021 19:51:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	05 Feb 2021 16:23:07
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:08
DataPoint Verified.		14 Apr 2021 19:51:03
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '03 Feb 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:07

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:08
DataPoint Verified.		14 Apr 2021 19:51:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:07



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:02:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:08
DataPoint Verified.		14 Apr 2021 19:51:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:24:42
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:07

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:02:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:08
DataPoint Verified.		14 Apr 2021 19:51:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '28 Feb 2021' reason for change: New Information	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:24:42
User entered empty.	Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:07

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:02:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:08
DataPoint Verified.		14 Apr 2021 19:51:09
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4)	
	Carrie Kibler (b) (4)	05 Feb 2021 16:23:07
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:02:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:08
User entered empty.	System	05 Feb 2021 16:23:07

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:08
User entered empty.	System	05 Feb 2021 16:23:07

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:08
User entered empty.	System	05 Feb 2021 16:23:07

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 01:43:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 01:43:10
Data point term sent to Coder	System	15 Apr 2021 20:20:04
Coding entries removed.	(b) (4), (b) (6)	15 Apr 2021 20:19:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 19:54:44
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:27:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 09:18:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Feb 2021 09:18:52
Data point term sent to Coder	System	05 Feb 2021 16:24:05
User entered 'Gabapentin'	Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:51

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:11
DataPoint Verified.		19 Apr 2021 22:02:53
User closed query 'As per source it is reported as Yes Please verify and reconcile.' (Site from CRA).		19 Apr 2021 22:01:56
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
Query 'As per source it is reported as Yes. Please verify and reconcile.' answered with 'data correction done in edc ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:19:23
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 20:19:10
User entered 'Yes (Y)' reason for change: Data Entry Error		15 Apr 2021 20:19:10
User opened query 'As per source it is reported as Yes. Please verify and reconcile.' (Site from CRA).		14 Apr 2021 19:56:18
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:51



US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:11
DataPoint Verified.		19 Apr 2021 22:03:06
User closed query 'As per source, it is for rectal pain for Seton Placement. Please verify and update as needed.' (Site from CRA).		19 Apr 2021 22:02:41
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
Query 'As per source, it is for rectal pain for Seton Placement. Please verify and update as needed.' answered with 'data correction done in edc ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:19:35
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 20:19:10
User entered 'PROPHYLAXES FOR RECTAL PAIN FOR SETON PLACEMENT' reason for change: Data Entry Error		15 Apr 2021 20:19:10
User opened query 'As per source, it is for rectal pain for Seton Placement. Please verify and update as needed.' (Site from CRA).		14 Apr 2021 19:55:37
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Fistulotomy'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:51

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:11
DataPoint Verified.		14 Apr 2021 19:56:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '300'	(b) (4)	
	Carrie Kibler (b) (4)	05 Feb 2021 16:23:51
	(b) (4)	

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:11
DataPoint Verified.		14 Apr 2021 19:56:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'mg (mg)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:51

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:02:10**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:11
DataPoint Verified.		14 Apr 2021 19:56:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4)	05 Feb 2021 16:23:51
	Carrie Kibler (b) (4)	
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:02:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:11
DataPoint Verified.		14 Apr 2021 19:56:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'three times daily (TID)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:51

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:02:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:11
DataPoint Verified.		14 Apr 2021 19:56:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	05 Feb 2021 16:23:51
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:02:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:11
DataPoint Verified.		14 Apr 2021 19:56:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Oral (ORAL)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:51

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:02:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:11
DataPoint Verified.		14 Apr 2021 19:56:34
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	05 Feb 2021 16:23:51
	(b) (4)	



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:11
DataPoint Verified.		14 Apr 2021 19:56:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '03 Feb 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:51

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:11
DataPoint Verified.		14 Apr 2021 19:56:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:51

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:02:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:11
DataPoint Verified.		14 Apr 2021 19:56:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:22:26
User entered 'Yes (Y)'	Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:51

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 10:02:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:11
DataPoint Verified.		14 Apr 2021 19:56:46
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '28 Feb 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:22:26
User entered empty.	Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:23:51

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:02:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:11
DataPoint Verified.		14 Apr 2021 19:56:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4)	
	Carrie Kibler (b) (4)	05 Feb 2021 16:23:51
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:02:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:11
User entered '3'	System	05 Feb 2021 16:23:51

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:11
User entered '1'	System	05 Feb 2021 16:23:51

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:11
User entered '804 (804)'	System	05 Feb 2021 16:23:51



US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:02:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:15
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: GAVILAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 20:21:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 20:21:07
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	15 Apr 2021 20:20:04 15 Apr 2021 20:19:53
DataPoint Verified.		14 Apr 2021 19:57:04
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:27:27
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: GAVILAX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 16:25:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Feb 2021 16:25:43
Data point term sent to Coder User entered 'Gavilax'	System Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:25:06 05 Feb 2021 16:24:33

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:02:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:15
DataPoint Verified.		23 Apr 2021 14:39:12
User closed query 'As per it is recorded as "Yes". Please verify and reconcile.' (Site from CRA).		23 Apr 2021 14:39:09
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
Query 'As per it is recorded as "Yes". Please verify and reconcile.' answered with 'data correction done in edc' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:20:02
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 20:19:53
User entered 'Yes (Y)' reason for change: Data Entry Error		15 Apr 2021 20:19:53
User opened query 'As per it is recorded as "Yes". Please verify and reconcile.' (Site from CRA).		14 Apr 2021 19:57:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:24:33

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:02:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:15
DataPoint Verified.		23 Apr 2021 14:39:20
User closed query 'As per source, it is for rectal pain for Seton Placement. Please verify and update as needed.' (Site from CRA).		23 Apr 2021 14:39:18
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
Query 'As per source, it is for rectal pain for Seton Placement. Please verify and update as needed.' answered with 'data correction done in edc' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:20:12
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 20:19:53
User entered 'PROPHYLAXES FOR RECTAL PAIN FOR SETON PLACEMENT' reason for change: Data Entry Error		15 Apr 2021 20:19:53
User opened query 'As per source, it is for rectal pain for Seton Placement. Please verify and update as needed.' (Site from CRA).		14 Apr 2021 19:58:06
DataPoint Un-verified.		14 Apr 2021 19:57:47
DataPoint Verified.		14 Apr 2021 19:57:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Fistulotomy'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:24:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:15
DataPoint Verified.		14 Apr 2021 19:58:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '17'	(b) (4)	
	Carrie Kibler (b) (4)	05 Feb 2021 16:24:33
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:15
DataPoint Verified.		14 Apr 2021 19:58:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'g (g)'	(b) (4)	
	Carrie Kibler (b) (4)	05 Feb 2021 16:24:33
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:02:10**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:15
DataPoint Verified.		14 Apr 2021 19:58:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4)	05 Feb 2021 16:24:33
	Carrie Kibler (b) (4)	
	(b) (4)	

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:02:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:15
DataPoint Verified.		14 Apr 2021 19:58:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'twice daily (BID)'	(b) (4)	
	Carrie Kibler (b) (4)	05 Feb 2021 16:24:33
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:02:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:15
DataPoint Verified.		14 Apr 2021 19:58:22
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4)	05 Feb 2021 16:24:33
	Carrie Kibler (b) (4)	
	(b) (4)	



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:02:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:15
DataPoint Verified.		14 Apr 2021 19:58:23
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Oral (ORAL)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:24:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:02:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:15
DataPoint Verified.		14 Apr 2021 19:58:25
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4)	05 Feb 2021 16:24:33
	Carrie Kibler (b) (4)	
	(b) (4)	

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:15
DataPoint Verified.		14 Apr 2021 19:58:26
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '03 Feb 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:24:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:15
DataPoint Verified.		14 Apr 2021 19:58:28
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '0'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:24:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:02:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:15
DataPoint Verified.		14 Apr 2021 19:58:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	01 Apr 2021 19:23:15
User entered 'Yes (Y)'	Carrie Kibler (b) (4)	05 Feb 2021 16:24:33
	(b) (4)	

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 10:02:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:15
DataPoint Verified.		14 Apr 2021 19:58:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '28 Feb 2021' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:23:15
User entered empty.	Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:24:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:02:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:15
DataPoint Verified.		14 Apr 2021 19:58:33
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:24:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:02:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:15
User entered '2'	System	05 Feb 2021 16:24:33



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:15
User entered '1'	System	05 Feb 2021 16:24:33

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:15
User entered '804 (804)'	System	05 Feb 2021 16:24:33

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:45
DataPoint Verified.		14 Apr 2021 19:59:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Apr 2021 10:47:36
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 10:47:36
Data point term sent to Coder	System	29 Mar 2021 20:55:52
User entered 'Spring Valley probiotic'	(b) (4), (b) (6)	29 Mar 2021 20:55:10
DataPoint activated with code reason code Data required.		29 Mar 2021 20:41:19
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	26 Mar 2021 23:14:14

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:45
DataPoint Verified.		14 Apr 2021 19:59:23
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Mar 2021 20:55:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Mar 2021 20:41:19
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	26 Mar 2021 23:14:14

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:45
DataPoint Verified.		14 Apr 2021 20:01:12
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'general health '	(b) (4), (b) (6)	29 Mar 2021 20:55:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Mar 2021 20:41:19
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	26 Mar 2021 23:14:14

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:10

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:45
DataPoint Verified.		14 Apr 2021 20:01:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'l'	(b) (4), (b) (6)	29 Mar 2021 20:55:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Mar 2021 20:41:19
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	26 Mar 2021 23:14:14

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:10

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:45
DataPoint Verified.		14 Apr 2021 20:01:20
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'capsule (CAPSULE)'	(b) (4), (b) (6)	29 Mar 2021 20:55:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Mar 2021 20:41:19
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	26 Mar 2021 23:14:14

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:10

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:45
DataPoint Verified.		14 Apr 2021 20:01:24
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:55:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Mar 2021 20:41:19
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	26 Mar 2021 23:14:14



US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:45
DataPoint Verified.		14 Apr 2021 20:01:34
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'once daily (QD)'	(b) (4), (b) (6)	29 Mar 2021 20:55:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Mar 2021 20:41:19
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	26 Mar 2021 23:14:14

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:10

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:45
DataPoint Verified.		14 Apr 2021 20:01:36
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:55:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Mar 2021 20:41:19
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	26 Mar 2021 23:14:14

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:10

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:45
DataPoint Verified.		14 Apr 2021 20:01:37
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Mar 2021 20:55:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Mar 2021 20:41:19
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	26 Mar 2021 23:14:14

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:10

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:45
DataPoint Verified.		14 Apr 2021 20:01:42
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4), (b) (6)	29 Mar 2021 20:55:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Mar 2021 20:41:19
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	26 Mar 2021 23:14:14

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:10

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:45
DataPoint Verified.		14 Apr 2021 20:01:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '24 Feb 2021'	(b) (4), (b) (6)	29 Mar 2021 20:55:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Mar 2021 20:41:19
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	26 Mar 2021 23:14:14

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:45
DataPoint Verified.		14 Apr 2021 20:01:44
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '0'	(b) (4), (b) (6)	29 Mar 2021 20:55:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Mar 2021 20:41:19
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	26 Mar 2021 23:14:14

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:10

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:45
DataPoint Verified.		14 Apr 2021 20:01:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 20:55:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Mar 2021 20:41:19
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	26 Mar 2021 23:14:14

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:10

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:45
DataPoint Verified.		14 Apr 2021 20:01:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '01 Mar 2021'	(b) (4), (b) (6)	29 Mar 2021 20:55:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Mar 2021 20:41:19
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	26 Mar 2021 23:14:14



US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 10:02:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:45
DataPoint Verified.		14 Apr 2021 20:01:56
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 20:55:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Mar 2021 20:41:19
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	26 Mar 2021 23:14:14

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:02:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:45
User entered '1'	System	29 Mar 2021 20:55:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Mar 2021 20:41:19
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	26 Mar 2021 23:14:14

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:45
User entered '1'	System	29 Mar 2021 20:55:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Mar 2021 20:41:19
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	26 Mar 2021 23:14:14

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:45
User entered '804 (804)'	System	29 Mar 2021 20:55:10
DataPoint activated with code reason code Data required.	(b) (4), (b) (6)	29 Mar 2021 20:41:19
DataPoint inactivated with code reason code Data not required.	Thea Marie Cordero (b) (4)	26 Mar 2021 23:14:14

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:02:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:49
DataPoint Verified.		14 Apr 2021 20:39:13
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE - 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	29 Mar 2021 21:08:26
Data point term sent to Coder	System	29 Mar 2021 21:06:17
User entered 'morphine sulfate'	(b) (4), (b) (6)	29 Mar 2021 21:06:01

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:02:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:49
DataPoint Verified.		14 Apr 2021 20:39:21
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:06:01

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:02:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:49
DataPoint Verified.		14 Apr 2021 20:39:23
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'SAE#3 PARTIAL SMALL BOWEL OBSTRUCTION' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:08:18
User entered 'SAE# Partial small bowel obstruction'	(b) (4), (b) (6)	29 Mar 2021 21:06:01

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:49
DataPoint Verified.		14 Apr 2021 20:39:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '4'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:06:01



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:49
DataPoint Verified.		14 Apr 2021 20:39:30
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:06:01

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:02:10**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:49
DataPoint Verified.		14 Apr 2021 20:44:38
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:06:01

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:02:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:49
User closed query 'As per Medical records,pg9-10 of 39, subject was dosed twice. Please verify and reconcile by making second entry for MORPHINE SULFATE.' (Site from CRA).		23 Apr 2021 14:39:52
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
Query 'As per Medical records,pg9-10 of 39, subject was dosed twice. Please verify and reconcile by making second entry for MORPHINE SULFATE.' answered with 'data updated in source doc and edc ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:02:31
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 21:01:53
User entered 'once daily (QD)' reason for change: Data Entry Error		15 Apr 2021 21:01:53
User opened query 'As per Medical records,pg9-10 of 39, subject was dosed twice. Please verify and reconcile by making second entry for MORPHINE SULFATE.' (Site from CRA).		14 Apr 2021 20:49:12
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:44:42
DataPoint Verified.		14 Apr 2021 20:41:07
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:06:01

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 10:02:10

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:49
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
Signature has been broken.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:01:53
User entered empty; reason for change Data Entry Error	(b) (4)	15 Apr 2021 21:01:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'every 4 hours as needed for pain'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:06:01

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:02:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:49
DataPoint Verified.		14 Apr 2021 20:44:44
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:06:01

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:02:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:49
DataPoint Verified.		14 Apr 2021 20:44:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:06:01

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:49
DataPoint Verified.		14 Apr 2021 20:44:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '21 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:06:01

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:49
DataPoint Verified.		14 Apr 2021 20:44:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:06:01



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:02:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:49
DataPoint Verified.		14 Apr 2021 20:46:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:06:01

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:02:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:49
DataPoint Verified.		14 Apr 2021 20:46:03
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:06:01

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:02:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:49
DataPoint Verified.		14 Apr 2021 20:46:05
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:06:01

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:02:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:49
User entered '1'	System	15 Apr 2021 21:01:53
User entered empty.	System	29 Mar 2021 21:06:01

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:49
User entered '1'	System	15 Apr 2021 21:01:53
User entered empty.	System	29 Mar 2021 21:06:01

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:49
User entered '804 (804)'	System	15 Apr 2021 21:01:53
User entered empty.	System	29 Mar 2021 21:06:01

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:02:10

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:53
DataPoint Verified.		14 Apr 2021 20:50:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4) (b) (4)	30 Mar 2021 09:41:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 09:41:59
Data point term sent to Coder	System	29 Mar 2021 21:08:26
User entered 'ondansetron'	(b) (4), (b) (6)	29 Mar 2021 21:07:50

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:02:10

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:53
DataPoint Verified.		23 Apr 2021 14:40:15
User closed query 'As per source it is recorded as NO. Please verify and update as needed.' (Site from CRA).		23 Apr 2021 14:40:13
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
Query 'As per source it is recorded as NO. Please verify and update as needed.' answered with 'data updated ' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:06:23
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 21:04:22
User entered 'No (N)' reason for change: Data Entry Error		15 Apr 2021 21:04:22
User opened query 'As per source it is recorded as NO. Please verify and update as needed.' (Site from CRA).		14 Apr 2021 20:58:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:07:50



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:02:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:53
DataPoint Verified.		14 Apr 2021 20:50:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'SAE#3 partial small bowel obstruction'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:07:50

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:53
DataPoint Verified.		14 Apr 2021 20:50:32
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '4'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:07:50

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:53
DataPoint Verified.		14 Apr 2021 20:50:34
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:07:50

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:02:10**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:53
DataPoint Verified.		14 Apr 2021 20:50:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:07:50

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 10:02:10

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:53
User closed query 'As per Medical records,pg9-10 of 39, subject was dosed twice. Please verify and reconcile by making second entry for Ondansetron. ' (Site from CRA).		23 Apr 2021 14:40:22
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
Query 'As per Medical records,pg9-10 of 39, subject was dosed twice. Please verify and reconcile by making second entry for Ondansetron. ' answered with 'data correction done in source doc for BID' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:10:46
Signature has been broken.	(b) (4), (b) (6)	15 Apr 2021 21:10:41
User entered 'twice daily (BID)' reason for change: Data Entry Error		15 Apr 2021 21:10:41
User opened query 'As per Medical records,pg9-10 of 39, subject was dosed twice. Please verify and reconcile by making second entry for Ondansetron. ' (Site from CRA).		14 Apr 2021 21:09:04
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 20:56:13
DataPoint Verified.		14 Apr 2021 20:50:37
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:07:50

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:02:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:53
DataPoint Un-verified.		14 Apr 2021 20:56:20
DataPoint Verified.		14 Apr 2021 20:55:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:07:50

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:02:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:53
DataPoint Verified.		14 Apr 2021 20:55:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:07:50

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:02:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:53
DataPoint Verified.		14 Apr 2021 20:55:52
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:07:50



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:53
DataPoint Verified.		14 Apr 2021 20:55:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '21 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:07:50

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:53
DataPoint Verified.		14 Apr 2021 20:55:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:07:50

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:02:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:53
DataPoint Verified.		14 Apr 2021 21:04:01
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:07:50

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:02:10**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:53
DataPoint Verified.		14 Apr 2021 21:04:31
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '21 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:07:50

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:02:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:53
DataPoint Verified.		14 Apr 2021 21:04:03
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 21:07:50

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:02:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:53
User entered '2'	System	15 Apr 2021 21:10:41
User entered empty.	System	29 Mar 2021 21:07:50

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:53
User entered '1'	System	15 Apr 2021 21:10:41
User entered empty.	System	29 Mar 2021 21:07:50

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:53
User entered '804 (804)'	System	15 Apr 2021 21:10:41
User entered empty.	System	29 Mar 2021 21:07:50



US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:02:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:56
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.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:04:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Apr 2021 14:04:48
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:09:09
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 13:38:32
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Apr 2021 13:38:32
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	02 Apr 2021 14:27:27
Data point term sent to Coder	System	01 Apr 2021 19:28:17
Data point term sent to Coder	System	01 Apr 2021 19:27:16
User entered 'SODIUM CHLORIDE'	(b) (4), (b) (6)	01 Apr 2021 19:26:48

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:02:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:56
DataPoint Verified.		14 Apr 2021 21:14:02
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:26:48

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:02:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:56
DataPoint Verified.		14 Apr 2021 21:14:03
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 19:27:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	01 Apr 2021 19:27:29
User entered 'SAE#3 PARTIAL SMALL BOWEL OBSTRUCTION' reason for change: New Information	(b) (4), (b) (6)	01 Apr 2021 19:27:29
User opened query 'Data is required. Please complete.' (Site from System).	System	01 Apr 2021 19:26:48
User entered empty.	(b) (4), (b) (6)	01 Apr 2021 19:26:48

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:56
DataPoint Verified.		14 Apr 2021 21:15:06
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '100'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:26:48

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:56
DataPoint Verified.		14 Apr 2021 21:15:35
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:26:48

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:02:10**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:56
DataPoint Verified.		14 Apr 2021 21:15:08
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'ML/HOUR'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:26:48

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:02:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:56
DataPoint Verified.		14 Apr 2021 21:15:37
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:26:48

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:02:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:56
DataPoint Verified.		14 Apr 2021 21:15:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'CONTINUOUS INFUSION'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:26:48



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:02:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:56
DataPoint Verified.		14 Apr 2021 21:15:41
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:26:48

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:02:10**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:56
DataPoint Verified.		14 Apr 2021 21:15:44
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:26:48

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:56
DataPoint Verified.		14 Apr 2021 21:16:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '21 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:26:48

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:56
DataPoint Verified.		14 Apr 2021 21:16:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:26:48

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:02:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:56
DataPoint Verified.		14 Apr 2021 21:16:48
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:26:48

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:02:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:56
DataPoint Verified.		14 Apr 2021 21:16:50
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '21 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:26:48

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 10:02:10

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:56
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 21:16:52
Signature has been broken.	Thea Marie Cordero (b) (4)	13 Apr 2021 22:05:40
User entered 'No (N)' reason for change: Data Entry Error	Thea Marie Cordero (b) (4)	13 Apr 2021 22:05:40
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:26:48

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:02:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:56
User entered empty.	System	01 Apr 2021 19:26:48



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:56
User entered empty.	System	01 Apr 2021 19:26:48

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:57:56
User entered empty.	System	01 Apr 2021 19:26:48

US3862144

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 10:02:10

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 09:19:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Apr 2021 09:19:29
User signature succeeded.	Hana El Sahly (b) (4) (b) (4)	15 Apr 2021 21:43:10
Data point term sent to Coder	System	15 Apr 2021 21:03:55
User entered 'morphine sulfate'	(b) (4), (b) (6)	15 Apr 2021 21:03:40

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:02:10**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:00
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:03:40

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:02:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:00
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
User entered 'SAE#3 PARTIAL SMALL BOWEL OBSTRUCTION'	(b) (4), (b) (6)	15 Apr 2021 21:03:40

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:00
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
User entered '2'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:03:40

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:02:10**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:00
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:03:40

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:02:10**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:00
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:03:40



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:02:10**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:00
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:03:40

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:02:10**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:00
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:03:40

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:02:10**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:00
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4), (b) (6)	15 Apr 2021 21:03:40

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:02:10**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:00
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:03:40

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:00
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:03:40

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:02:10**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:00
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:03:40

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:02:10**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:00
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:03:40

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:02:10**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:00
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:03:40



**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:02:10**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:00
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 21:03:40

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:02:10**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:00
User entered '1'	System	15 Apr 2021 21:03:40

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:00
User entered '1'	System	15 Apr 2021 21:03:40

**US3862144**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 10:02:10**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 12:58:00
User entered '804 (804)'	System	15 Apr 2021 21:03:40

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 10:02:10

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 07:04:48
DataPoint Verified.		14 Apr 2021 21:17:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Yes (Y)'	(b) (4)	
	Carrie Kibler (b) (4)	02 Dec 2020 22:42:11
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:02:10

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '02 Dec 2020' reason for change: Data Entry Error	(b) (4)	24 Mar 2021 22:22:35
User entered '2 Dec 2020'	Carrie Kibler (b) (4)	02 Dec 2020 22:43:12
	(b) (4)	

US3862144

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:02:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'colonoscopy'	(b) (4) Carrie Kibler (b) (4) (b) (4)	02 Dec 2020 22:43:12

US3862144

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:02:10

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User closed query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 08:30:50
Query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify. ' answered with 'updated in source and edc.' (Site from DM).	Carrie Kibler (b) (4) (b) (4)	24 Mar 2021 22:23:18
User entered 'Adverse Event (AE)' reason for change: Per Query Resolution	Carrie Kibler (b) (4) (b) (4)	24 Mar 2021 22:22:35
User opened query 'Per DM CLR: Indication = OTHER, however, the noted medical condition in the Other, specify field is recorded in the AE eCRF page. Please reconcile and confirm if indication should recorded as one of the available options (i.e. Adverse Event) as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 11:03:49
User entered 'Other (OTHER)'	Carrie Kibler (b) (4) (b) (4)	02 Dec 2020 22:43:12



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 10:02:10

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty; reason for change Per Query Resolution	(b) (4) Carrie Kibler (b) (4)	24 Mar 2021 22:22:35
User entered 'follow up to perirectal abscess'	(b) (4) Carrie Kibler (b) (4)	02 Dec 2020 22:43:12

US3862144

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:02:10

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:53
DataPoint Verified.		14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '22 Jan 2021'	(b) (4)	
	Carrie Kibler (b) (4)	05 Feb 2021 16:02:08
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:02:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:53
DataPoint Verified.		14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'mri'	(b) (4)	
	Carrie Kibler (b) (4)	05 Feb 2021 16:02:08
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:02:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:53
DataPoint Verified.		14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	05 Feb 2021 16:02:14
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	05 Feb 2021 16:02:08
User entered 'Adverse Event (AE)'	Carrie Kibler (b) (4)	05 Feb 2021 16:02:08
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 10:02:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:53
DataPoint Verified.		14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
User entered empty; reason for change Data Entry Error	Carrie Kibler (b) (4)	05 Feb 2021 16:02:14
	(b) (4)	
User entered 'anal fistula'	Carrie Kibler (b) (4)	05 Feb 2021 16:02:08
	(b) (4)	

**US3862144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (3)**

**Generated On: 10 Jun 2021 10:02:10**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:57
DataPoint Verified.		14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '03 Feb 2021'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:02:35

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:02:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:57
DataPoint Verified.		14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'seton placement' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	29 Mar 2021 21:09:45
User entered 'fistulotomy'	Carrie Kibler (b) (4)	05 Feb 2021 16:02:35
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:02:10

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:57
DataPoint Verified.		14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Adverse Event (AE)'	(b) (4) Carrie Kibler (b) (4) (b) (4)	05 Feb 2021 16:02:35



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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 10 Jun 2021 10:02:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:52:57
DataPoint Verified.		14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4)	
	Carrie Kibler (b) (4)	05 Feb 2021 16:02:35
	(b) (4)	

**US3862144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 10:02:10**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:00
DataPoint Verified.		14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '21 Feb 2021' reason for change: Data Entry Error	(b) (4)	01 Apr 2021 19:35:31
User entered '02 Feb 2021'	(b) (4), (b) (6)	01 Apr 2021 19:28:52

**US3862144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:00
DataPoint Verified.		14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'ELECTROCARDIOGRAM'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:28:52

**US3862144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:00
DataPoint Verified.		14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:28:52

**US3862144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (4)**

**Generated On: 10 Jun 2021 10:02:10**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:00
DataPoint Verified.		14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:28:52

**US3862144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Procedure/Surgery date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '21 Feb 2021' reason for change: Data Entry Error	(b) (4)	01 Apr 2021 19:35:12
User entered '02 Feb 2021'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 10 Jun 2021 10:02:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 21:21:54
Signature has been broken.	Thea Marie Cordero	13 Apr 2021 22:29:04
	(b) (4)	
User entered 'CT ABDOMEN AND PELVIS'	Thea Marie Cordero	13 Apr 2021 22:29:04
reason for change: New Information	(b) (4)	
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
User entered 'CT ABDOMEN'	(b) (4), (b) (6)	01 Apr 2021 19:29:38

**US3862144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:29:38



**US3862144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (5)**

**Generated On: 10 Jun 2021 10:02:10**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:29:38

US3862144

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:02:10

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:08
DataPoint Verified.		14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:30:23

**US3862144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 10 Jun 2021 10:02:10**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:08
DataPoint Verified.		14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'NGT PLACEMENT'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:30:23

**US3862144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (6)**

**Generated On: 10 Jun 2021 10:02:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:08
DataPoint Verified.		14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:30:23

US3862144

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 10 Jun 2021 10:02:10

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:08
DataPoint Verified.		14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:30:23

**US3862144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 10 Jun 2021 10:02:10**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:36:17

US3862144

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 10 Jun 2021 10:02:10

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 21:21:54
Signature has been broken.	Thea Marie Cordero (b) (4)	13 Apr 2021 22:28:45
User entered 'ABDOMINAL X-RAY' reason for change: New Information	Thea Marie Cordero (b) (4)	13 Apr 2021 22:28:45
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'X-RAY NGT CONFIRMATION' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:37:02
User entered 'NGT PLACEMENT'		01 Apr 2021 19:36:17

**US3862144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 10 Jun 2021 10:02:10**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:36:17



**US3862144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (7)**

**Generated On: 10 Jun 2021 10:02:10**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:36:17

**US3862144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (8)**

**Generated On: 10 Jun 2021 10:02:10**

**Procedure/Surgery date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:16
DataPoint Verified.		14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '22 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:37:27

**US3862144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (8)**

**Generated On: 10 Jun 2021 10:02:10**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:16
DataPoint Verified.		14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'NGT REMOVAL'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:37:27

**US3862144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (8)**

**Generated On: 10 Jun 2021 10:02:10**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:16
DataPoint Verified.		14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:37:27

**US3862144**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (8)**

**Generated On: 10 Jun 2021 10:02:10**

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:53:16
DataPoint Verified.		14 Apr 2021 21:21:54
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 19:37:27

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'USA-US121-2021-MRNA-1273-P301000003'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Yes (Y)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42



**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Yes (Y)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:26
Reviewed for Safety.		14 Apr 2021 15:26:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
Un-reviewed for Safety.	System	29 Mar 2021 13:34:33
User entered 'Thea Marie'	System	29 Mar 2021 13:34:33
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Hana'	System	01 Mar 2021 15:56:42

US3862144

Folder: SAE USA-US121-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:24
Reviewed for Safety.		14 Apr 2021 15:26:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
Un-reviewed for Safety.	System	29 Mar 2021 13:34:33
User entered 'Cordero'	System	29 Mar 2021 13:34:33
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'El Sahly'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:21
Reviewed for Safety.		14 Apr 2021 15:26:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Un-reviewed for Safety.	(b) (4)	
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	29 Mar 2021 13:34:33
Reviewed for Safety.	System	29 Mar 2021 13:34:33
	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'One Baylor Plaza'	System	01 Mar 2021 15:56:42



**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Houston'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'TX'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered '77030'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:11
User entered 'US'	System	01 Mar 2021 15:57:07

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 18:29:26
User entered '4'	System	16 Apr 2021 12:47:31
User entered '3'	System	14 Apr 2021 15:26:19
User entered '2'	System	29 Mar 2021 13:34:33
User entered '1'	System	01 Mar 2021 15:57:07

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'USA-US121-2021-MRNA-1273-P301000003'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Yes (Y)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42



**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Yes (Y)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:26
Reviewed for Safety.		14 Apr 2021 15:26:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
Un-reviewed for Safety.	System	29 Mar 2021 13:34:33
User entered 'Thea Marie'	System	29 Mar 2021 13:34:33
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Hana'	System	01 Mar 2021 15:56:42

US3862144

Folder: SAE USA-US121-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:24
Reviewed for Safety.		14 Apr 2021 15:26:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
Un-reviewed for Safety.	System	29 Mar 2021 13:34:33
User entered 'Cordero'	System	29 Mar 2021 13:34:33
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'El Sahly'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:21
Reviewed for Safety.		14 Apr 2021 15:26:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Un-reviewed for Safety.	(b) (4)	
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	29 Mar 2021 13:34:33
Reviewed for Safety.	System	29 Mar 2021 13:34:33
	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'One Baylor Plaza'	System	01 Mar 2021 15:56:42



**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Houston'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'TX'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered '77030'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:11
User entered 'US'	System	01 Mar 2021 15:57:07

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 18:29:26
User entered '4'	System	16 Apr 2021 12:47:31
User entered '3'	System	14 Apr 2021 15:26:19
User entered '2'	System	29 Mar 2021 13:34:33
User entered '1'	System	01 Mar 2021 15:57:07

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 10:02:10**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:27
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '01/Mar/2021 10:57'	(b) (4) System	01 Mar 2021 15:57:07

US3862144

Folder: SAE USA-US121-2021-MRNA-1273-P301000003

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 10:02:10

**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)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:29
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:57:11
User entered 'I'	(b) (4), (b) (6)	01 Mar 2021 15:57:07

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'USA-US121-2021-MRNA-1273-P301000003'	System	01 Mar 2021 15:56:42



**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Yes (Y)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Yes (Y)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

US3862144

Folder: SAE USA-US121-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:26
Reviewed for Safety.		14 Apr 2021 15:26:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
Un-reviewed for Safety.	System	29 Mar 2021 13:34:33
User entered 'Thea Marie'	System	29 Mar 2021 13:34:33
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Hana'	System	01 Mar 2021 15:56:42



US3862144

Folder: SAE USA-US121-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:24
Reviewed for Safety.		14 Apr 2021 15:26:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
Un-reviewed for Safety.	System	29 Mar 2021 13:34:33
User entered 'Cordero'	System	29 Mar 2021 13:34:33
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'El Sahly'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:21
Reviewed for Safety.		14 Apr 2021 15:26:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
Un-reviewed for Safety.	System	29 Mar 2021 13:34:33
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	29 Mar 2021 13:34:33
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'One Baylor Plaza'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Houston'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'TX'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered '77030'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:11
User entered 'US'	System	01 Mar 2021 15:57:07

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 18:29:26
User entered '4'	System	16 Apr 2021 12:47:31
User entered '3'	System	14 Apr 2021 15:26:19
User entered '2'	System	29 Mar 2021 13:34:33
User entered '1'	System	01 Mar 2021 15:57:07

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 10:02:10**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:39
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered '29/Mar/2021 06:34'	(b) (4) System	29 Mar 2021 13:34:33



US3862144

Folder: SAE USA-US121-2021-MRNA-1273-P301000003

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 10:02:10

**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)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:41
Reviewed for Safety.		14 Apr 2021 15:26:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 13:34:33

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'USA-US121-2021-MRNA-1273-P301000003'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Yes (Y)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Yes (Y)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42



**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:26
Reviewed for Safety.		14 Apr 2021 15:26:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
Un-reviewed for Safety.	System	29 Mar 2021 13:34:33
User entered 'Thea Marie'	System	29 Mar 2021 13:34:33
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Hana'	System	01 Mar 2021 15:56:42

US3862144

Folder: SAE USA-US121-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:24
Reviewed for Safety.		14 Apr 2021 15:26:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
Un-reviewed for Safety.	System	29 Mar 2021 13:34:33
User entered 'Cordero'	System	29 Mar 2021 13:34:33
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'El Sahly'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:21
Reviewed for Safety.		14 Apr 2021 15:26:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Un-reviewed for Safety.	(b) (4)	
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	29 Mar 2021 13:34:33
Reviewed for Safety.	System	29 Mar 2021 13:34:33
	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'One Baylor Plaza'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Houston'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'TX'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered '77030'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:11
User entered 'US'	System	01 Mar 2021 15:57:07



**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 18:29:26
User entered '4'	System	16 Apr 2021 12:47:31
User entered '3'	System	14 Apr 2021 15:26:19
User entered '2'	System	29 Mar 2021 13:34:33
User entered '1'	System	01 Mar 2021 15:57:07

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 10:02:10**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 18:12:48
User entered '14/Apr/2021 10:26'	System	14 Apr 2021 15:26:19

US3862144

Folder: SAE USA-US121-2021-MRNA-1273-P301000003

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 10:02:10

**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)	16 Apr 2021 12:47:19
User signature succeeded.	Hana El Sahly (b) (4)	15 Apr 2021 21:43:10
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:49
User entered 'I'	(b) (4), (b) (6)	14 Apr 2021 15:26:19

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'USA-US121-2021-MRNA-1273-P301000003'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Yes (Y)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Yes (Y)'	System	01 Mar 2021 15:56:42



**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:26
Reviewed for Safety.		14 Apr 2021 15:26:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
Un-reviewed for Safety.	System	29 Mar 2021 13:34:33
User entered 'Thea Marie'	System	29 Mar 2021 13:34:33
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Hana'	System	01 Mar 2021 15:56:42

US3862144

Folder: SAE USA-US121-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:24
Reviewed for Safety.		14 Apr 2021 15:26:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
Un-reviewed for Safety.	System	29 Mar 2021 13:34:33
User entered 'Cordero'	System	29 Mar 2021 13:34:33
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'El Sahly'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:21
Reviewed for Safety.		14 Apr 2021 15:26:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Un-reviewed for Safety.	(b) (4)	
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	29 Mar 2021 13:34:33
Reviewed for Safety.	System	29 Mar 2021 13:34:33
	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'One Baylor Plaza'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Houston'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'TX'	System	01 Mar 2021 15:56:42



**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered '77030'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:11
User entered 'US'	System	01 Mar 2021 15:57:07

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 18:29:26
User entered '4'	System	16 Apr 2021 12:47:31
User entered '3'	System	14 Apr 2021 15:26:19
User entered '2'	System	29 Mar 2021 13:34:33
User entered '1'	System	01 Mar 2021 15:57:07

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 10:02:10**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	23 Apr 2021 14:01:29
	(b) (4)	
User entered '16/Apr/2021 08:47'	System	16 Apr 2021 12:47:31

US3862144

Folder: SAE USA-US121-2021-MRNA-1273-P301000003

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 10:02:10

**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)	23 Apr 2021 14:01:29
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 12:47:31

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:12:00
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'USA-US121-2021-MRNA-1273-P301000003'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:59
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Yes (Y)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:57
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42



**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:55
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:53
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Yes (Y)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:51
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:49
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:47
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'No (N)'	System	01 Mar 2021 15:56:42

US3862144

Folder: SAE USA-US121-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:10

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:26
Reviewed for Safety.		14 Apr 2021 15:26:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
Un-reviewed for Safety.	System	29 Mar 2021 13:34:33
User entered 'Thea Marie'	System	29 Mar 2021 13:34:33
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Hana'	System	01 Mar 2021 15:56:42

US3862144

Folder: SAE USA-US121-2021-MRNA-1273-P301000003

Form: Safety Report Form

Generated On: 10 Jun 2021 10:02:10

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:24
Reviewed for Safety.		14 Apr 2021 15:26:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
	(b) (4)	
Un-reviewed for Safety.	System	29 Mar 2021 13:34:33
User entered 'Cordero'	System	29 Mar 2021 13:34:33
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'El Sahly'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:21
Reviewed for Safety.		14 Apr 2021 15:26:04
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Un-reviewed for Safety.	(b) (4)	
User entered 'One Baylor Plaza, MS 280, Room 221D'	System	29 Mar 2021 13:34:33
Reviewed for Safety.	System	29 Mar 2021 13:34:33
	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'One Baylor Plaza'	System	01 Mar 2021 15:56:42



**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:19
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'Houston'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:17
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered 'TX'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:15
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:00
User entered '77030'	System	01 Mar 2021 15:56:42

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 18:11:14
User signature succeeded.	Hana El Sahly (b) (4)	02 Apr 2021 14:27:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 15:57:11
User entered 'US'	System	01 Mar 2021 15:57:07

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 10:02:10**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	26 Apr 2021 18:29:26
User entered '4'	System	16 Apr 2021 12:47:31
User entered '3'	System	14 Apr 2021 15:26:19
User entered '2'	System	29 Mar 2021 13:34:33
User entered '1'	System	01 Mar 2021 15:57:07

**US3862144**

**Folder: SAE USA-US121-2021-MRNA-1273-P301000003**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 10:02:10**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Hana El Sahly (b) (4)	28 Apr 2021 22:04:15
	(b) (4)	
User entered '26/Apr/2021 14:29'	System	26 Apr 2021 18:29:26

US3862144

Folder: SAE USA-US121-2021-MRNA-1273-P301000003

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 10:02:10

**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 22:04:15
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Apr 2021 18:29:26