

US3812081 (Prod: Sundance Clinical Research - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:54:48

All time stamps listed in this document are displayed in GMT

US3812081

Form: Participant Creation

Data signed: (b) (4) 20 Feb 2021 19:38:53

Generated On: 10 Jun 2021 09:54:48

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Participant ID

US3812081

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

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US3812081

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:38:54

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

Visit date (dd MMM yyyy)	07 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	SCRN
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US3812081

Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Feb 2021 19:38:54

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Date of Birth (MMM yyyy)	(b) (6) 1972
Age	47
Age Units	YEARS
Age (Derived)	47
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 20 Feb 2021 19:38:54

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Date of Informed Consent (*dd MMM yyyy*) 7 AUG 2020

Month and Year of Informed Consent (derived) AUG 2020

Year of Informed Consent (derived) 2020

Protocol Version

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

Was participant enrolled in the study?

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

If No, indicate reason for screen fail

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

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

Was this participant screened previously?

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

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

Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 20 Feb 2021 19:38:54

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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) 20 Feb 2021 19:38:54

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 20 Feb 2021 19:38:54

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Condition	BILATERAL VISUAL IMPAIRMENT
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Start Year (derived)	1987
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 20 Feb 2021 19:38:54

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Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 20 Feb 2021 19:38:54

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Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	18 OCT 2017
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)	OCT 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 20 Feb 2021 19:38:54

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Condition	VITAMIN D DEFICIENCY
Start date (dd MMM yyyy)	18 OCT 2017
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)	OCT 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 20 Feb 2021 19:38:54

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Condition	LIPOPROTEIN DEFICIENCY DISORDER
Start date (dd MMM yyyy)	18 OCT 2017
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)	OCT 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 20 Feb 2021 19:38:54

Generated On: 10 Jun 2021 09:54:48

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 19:38:54

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 AUG 2020
Time of assessment (00:00-23:59)	16:16 (24 HR)
Vital Signs Date and Time (derived)	7 AUG 2020 16:16
Height (xxx.x)	72.5 in
Weight (xxx.x)	233.0 lb
BMI (xxx.x)	31.23128 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	ND - Not Done
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:38:54

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 19:38:54

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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** True

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



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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 20 Feb 2021 19:38:54

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:38:54

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Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 20 Feb 2021 19:38:54

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What was the date of randomization? (dd MMM yyyy) 07 AUG 2020

What was the participant's randomization number? 102252

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 20 Feb 2021 19:38:54

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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) 20 Feb 2021 19:38:54

Generated On: 10 Jun 2021 09:54:48

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)	7 AUG 2020
Time of assessment (00:00-23:59)	16:16 (24 HR)
Vital Signs Date and Time (derived)	7 AUG 2020 16:16
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 19:38:54

Generated On: 10 Jun 2021 09:54:48

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)	7 AUG 2020
Time of assessment (00:00-23:59)	17:43 (24 HR)
Vital Signs Date and Time (derived)	7 AUG 2020 17:43
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	58 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:38:54

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Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 19:38:54

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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 AUG 2020

What was the treatment time? (00:00-23:59) 17:12 (24 HR)

Treatment Date and Time (derived) 7 AUG 2020 17:12

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

What was the frequency of the study treatment dosing? ONCE

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



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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 19:38:54

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Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

7 AUG 2020

Collection time (00:00-23:59)

17:07 (24 HR)

Collection date and time (derived)

7 AUG 2020 17:07

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 19:38:54

Generated On: 10 Jun 2021 09:54:48

Collection date (dd MMM yyyy)			7 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:09	7 AUG 2020 17:09
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:38:54

Generated On: 10 Jun 2021 09:54:48

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 09:54:48

**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

97.0 °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

07 AUG 2020 17:47

PC Open Date & Time

07 AUG 2020 17:32

PC Close Date & Time

07 AUG 2020 20:02

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

**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 97.0 °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	07 AUG 2020 22:28
PC Open Date & Time	07 AUG 2020 20:57
PC Close Date & Time	08 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:54:48

**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

98.0 °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

08 AUG 2020 21:20

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:54:48

**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 AUG 2020 19:26

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:54:48

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**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

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 19:26

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:54:48

**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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 05:54

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 AUG 2020 19:09

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 21:18

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

**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

07 AUG 2020 17:48

PC Open Date & Time

07 AUG 2020 17:32

PC Close Date & Time

07 AUG 2020 20:02

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

**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 AUG 2020 22:29

PC Open Date & Time

07 AUG 2020 20:57

PC Close Date & Time

08 AUG 2020 11:59

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:54:48

**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 ☐

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

25

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 - **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 AUG 2020 21:24

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:54:48

**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 AUG 2020 19:26

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:54:48

**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 AUG 2020 19:26

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59



US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:54:48

**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 AUG 2020 05:54

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:54:48

**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

12 AUG 2020 19:09

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:54:48

**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

13 AUG 2020 21:18

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

**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 ☐

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 17:48
PC Open Date & Time	07 AUG 2020 17:32
PC Close Date & Time	07 AUG 2020 20:02

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

**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 ☐

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

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

No ☒

Yes ☐

PC Time stamp	07 AUG 2020 22:29
PC Open Date & Time	07 AUG 2020 20:57
PC Close Date & Time	08 AUG 2020 11:59

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:54:48

**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 ☒



US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:54:48

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 21:24
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:54:48

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 ☒

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:54:48

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 19:26
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:54:48

**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 ☒

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:54:48

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 19:26
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:54:48

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:54:48

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 05:54
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:54:48

**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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US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:54:48

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 19:09
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:54:48

**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 ☒

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:54:48

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 21:18
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3812081

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:38:54

Generated On: 10 Jun 2021 09:54:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812081

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:38:53

Generated On: 10 Jun 2021 09:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812081

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:38:53

Generated On: 10 Jun 2021 09:54:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812081

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:38:53

Generated On: 10 Jun 2021 09:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:38:53

Generated On: 10 Jun 2021 09:54:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3812081

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:38:53

Generated On: 10 Jun 2021 09:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:38:54

Generated On: 10 Jun 2021 09:54:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 19:38:54

Generated On: 10 Jun 2021 09:54:48

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	16:30 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 16:30
Temperature (xxx.x)	98.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	47 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 19:38:54

Generated On: 10 Jun 2021 09:54:48

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 SEP 2020
Time of assessment (00:00-23:59)	17:51 (24 HR)
Vital Signs Date and Time (derived)	2 SEP 2020 17:51
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	47 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG

US3812081

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:38:54

Generated On: 10 Jun 2021 09:54:48

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3812081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 19:38:54

Generated On: 10 Jun 2021 09:54:48

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) 2 SEP 2020

What was the treatment time? (00:00-23:59) 17:20 (24 HR)

Treatment Date and Time (derived) 2 SEP 2020 17:20

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

US3812081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 19:38:54

Generated On: 10 Jun 2021 09:54:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 SEP 2020
Collection time (00:00-23:59)	17:03 (24 HR)
Collection date and time (derived)	2 SEP 2020 17:03

US3812081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 19:38:54

Generated On: 10 Jun 2021 09:54:48

Collection date (dd MMM yyyy)			2 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:06	2 SEP 2020 17:06
Nasopharyngeal Swab 2	No		



US3812081

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:38:54

Generated On: 10 Jun 2021 09:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

**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

97.1 °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

02 SEP 2020 17:54

PC Open Date & Time

02 SEP 2020 17:40

PC Close Date & Time

02 SEP 2020 20:10

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

**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 97.1 °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	03 SEP 2020 06:10
PC Open Date & Time	02 SEP 2020 21:05
PC Close Date & Time	03 SEP 2020 11:59

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:54:48

**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

99.6 °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

03 SEP 2020 19:27

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:54:48

**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

96.6 °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

05 SEP 2020 09:36

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.0 °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

06 SEP 2020 08:51

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:54:48

**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

97.1 °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

06 SEP 2020 21:11

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:54:48

**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

98.4 °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 06:14

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59



US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 22:17

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

**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

02 SEP 2020 17:54

PC Open Date & Time

02 SEP 2020 17:40

PC Close Date & Time

02 SEP 2020 20:10

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

**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

03 SEP 2020 06:10

PC Open Date & Time

02 SEP 2020 21:05

PC Close Date & Time

03 SEP 2020 11:59

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:54:48

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

80

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

03 SEP 2020 19:29

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:54:48

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

90

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

05 SEP 2020 09:35

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:54:48

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

32

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

06 SEP 2020 08:49

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:54:48

**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

06 SEP 2020 21:12

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:54:48

**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

08 SEP 2020 06:14

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59



US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:54:48

**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

08 SEP 2020 22:17

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

**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 ☐

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 17:55
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PC Open Date & Time	02 SEP 2020 17:40
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PC Close Date & Time	02 SEP 2020 20:10
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US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

**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 ☐

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

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

No ☒

Yes ☐

PC Time stamp	03 SEP 2020 06:11
PC Open Date & Time	02 SEP 2020 21:05
PC Close Date & Time	03 SEP 2020 11:59

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:54:48

**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 ☒

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:54:48

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 19:30
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:54:48

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 ☒



US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:54:48

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 09:35
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:54:48

**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 ☒

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:54:48

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 08:50
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 5

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:54:48

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 21:12
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:54:48

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 ☒

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:54:48

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 06:15
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:54:48

**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 ☒



US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:54:48

Yes <input type="checkbox"/>	
PC Time stamp	08 SEP 2020 22:16
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3812081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:38:53

Generated On: 10 Jun 2021 09:54:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812081

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:38:53

Generated On: 10 Jun 2021 09:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:38:53

Generated On: 10 Jun 2021 09:54:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812081

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:38:53

Generated On: 10 Jun 2021 09:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:38:53

Generated On: 10 Jun 2021 09:54:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812081

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:38:53

Generated On: 10 Jun 2021 09:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:38:54

Generated On: 10 Jun 2021 09:54:48

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	1 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3



US3812081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 19:38:54

Generated On: 10 Jun 2021 09:54:48

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	1 OCT 2020
Time of assessment ( <i>00:00-23:59</i> )	16:05 (24 HR)
Vital Signs Date and Time (derived)	1 OCT 2020 16:05
Temperature ( <i>xxx.x</i> )	96.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	60 beats/min
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	74 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812081

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:38:54

Generated On: 10 Jun 2021 09:54:48

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3812081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 19:38:54

Generated On: 10 Jun 2021 09:54:48

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	1 OCT 2020
Collection time (00:00-23:59)	16:15 (24 HR)
Collection date and time (derived)	1 OCT 2020 16:15

US3812081

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:38:54

Generated On: 10 Jun 2021 09:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

<b>TIMEPOINT</b>	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 OCT 2020 08:11:38
Patient Cloud Open Date & Time	07 OCT 2020 00:01
Patient Cloud Close Date & Time	11 OCT 2020 23:59

US3812081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 OCT 2020 16:56:18

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3812081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 OCT 2020 14:16:11

Patient Cloud Open Date & Time

21 OCT 2020 00:01

Patient Cloud Close Date & Time

25 OCT 2020 23:59

US3812081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 03:24:47

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59



US3812081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 05:32:11

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3812081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 NOV 2020 04:42:06

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 NOV 2020 15:40:40
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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

30 NOV 2020 11:32:55

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 08:55:53

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 06:48:30

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 22:57:08

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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

28 DEC 2020 10:54:06

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59



US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 JAN 2021 19:04:19

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 23:09:45

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 JAN 2021 08:23:37

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 JAN 2021 10:55:30

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 FEB 2021 09:24:50

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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

07 FEB 2021 07:25:46

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 FEB 2021 07:14:45
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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

21 FEB 2021 20:35:27

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59



US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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

28 FEB 2021 06:02:10

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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

07 MAR 2021 01:40:18

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 MAR 2021 06:49:06

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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

24 MAR 2021 13:21:22

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	31 MAR 2021 16:42:45
Patient Cloud Open Date & Time	28 MAR 2021 00:01
Patient Cloud Close Date & Time	01 APR 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 APR 2021 00:18:04

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 11:13:08

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 21:40:06

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59



US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 APR 2021 06:35:24

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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13 MAY 2021 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 285

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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03 JUN 2021 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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17 JUN 2021 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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"/>



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 334

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

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

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

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

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

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

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

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

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

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



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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22 JUL 2021 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 355

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

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

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

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

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

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

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

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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05 AUG 2021 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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12 AUG 2021 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	22 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	26 AUG 2021 23:59
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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	05 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 SEP 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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"/>



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 SEP 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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="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"/>

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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23 SEP 2021 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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="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"/>

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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30 SEP 2021 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	17 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 OCT 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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"/>

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	24 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	28 OCT 2021 23:59
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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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"/>

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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="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"/>



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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11 NOV 2021 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

14 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

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

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 488

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

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

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

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

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

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

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

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



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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09 DEC 2021 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

16 DEC 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	26 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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"/>

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

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03 FEB 2022 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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13 FEB 2022 00:01

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17 FEB 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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24 FEB 2022 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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03 MAR 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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10 MAR 2022 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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17 MAR 2022 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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20 MAR 2022 00:01

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24 MAR 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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



**US3812081**

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

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**Generated On: 10 Jun 2021 09:54:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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27 MAR 2022 00:01

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31 MAR 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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"/>

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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07 APR 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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"/>

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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10 APR 2022 00:01

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14 APR 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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17 APR 2022 00:01

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21 APR 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

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

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



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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="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"/>

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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"/>

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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09 JUN 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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"/>

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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30 JUN 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

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

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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07 JUL 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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14 JUL 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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21 JUL 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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11 AUG 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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"/>



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	14 AUG 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 AUG 2022 23:59
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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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01 SEP 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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15 SEP 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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22 SEP 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

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[Patient Cloud Close Date & Time](#)

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29 SEP 2022 23:59

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US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

**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 ☐

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

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02 OCT 2022 00:01

---

[Patient Cloud Close Date & Time](#)

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06 OCT 2022 23:59

---

US3812081

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

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



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

---

Date and time of submission

---

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

---

US3812081

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:54:48

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		28 FEB 2021 06:01:56

US3812081

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:38:54

Generated On: 10 Jun 2021 09:54:48

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*

US3812081

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:38:54

Generated On: 10 Jun 2021 09:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812081

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:38:53

Generated On: 10 Jun 2021 09:54:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812081

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:38:53

Generated On: 10 Jun 2021 09:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812081

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:38:53

Generated On: 10 Jun 2021 09:54:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812081

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:38:53

Generated On: 10 Jun 2021 09:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3812081

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:38:53

Generated On: 10 Jun 2021 09:54:48

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812081

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:38:53

Generated On: 10 Jun 2021 09:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812081

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 20:56:40

Generated On: 10 Jun 2021 09:54:48

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

Visit date (dd MMM yyyy)	03 MAR 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3812081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 00:48:59

Generated On: 10 Jun 2021 09:54:48

Were vital signs assessed? Yes ☐  
No ☒

Date of assessment (dd MMM yyyy) \_\_\_\_\_

Time of assessment (00:00-23:59) \_\_\_\_\_

Vital Signs Date and Time (derived) \_\_\_\_\_

Temperature (xxx.x) \_\_\_\_\_

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

If Other, specify \_\_\_\_\_

Pulse (xxx) \_\_\_\_\_

Pulse units \_\_\_\_\_

Respiratory Rate (xxx) \_\_\_\_\_

Respiratory Rate units \_\_\_\_\_

Systolic Blood Pressure (xxx) \_\_\_\_\_

Systolic Blood Pressure units \_\_\_\_\_

Diastolic Blood Pressure (xxx) \_\_\_\_\_

Diastolic Blood Pressure units \_\_\_\_\_

Height (derived) \_\_\_\_\_

Weight (derived) \_\_\_\_\_

US3812081

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 20:56:40

Generated On: 10 Jun 2021 09:54:48

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3812081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 20:56:40

Generated On: 10 Jun 2021 09:54:48

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

Collection date (dd MMM yyyy)	03 MAR 2021
-------------------------------	-------------

Collection time (00:00-23:59)	16:10 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	03 MAR 2021 16:10
------------------------------------	-------------------

US3812081

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 20:56:40

Generated On: 10 Jun 2021 09:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812081

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 00:48:59

Generated On: 10 Jun 2021 09:54:48

Was Contact Attempted? Yes ☒  
No ☐

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

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

Comments

*If Contact Not Made, please provide Comments*



US3812081

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 00:48:59

Generated On: 10 Jun 2021 09:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812081

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 15:16:42

Generated On: 10 Jun 2021 09:54:48

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 30 APR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3812081

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 15:16:42

Generated On: 10 Jun 2021 09:54:48

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3812081**

**Folder: Safety Call Day 299 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

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*

**US3812081**

**Folder: Safety Call Day 299 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:54:48**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3812081

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:54:48

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

US3812081

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 20 Feb 2021 19:38:53

Generated On: 10 Jun 2021 09:54:48

---

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

---

US3812081

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

Form: Visit Date

Data signed: (b) (4) 26 Mar 2021 20:56:40

Generated On: 10 Jun 2021 09:54:48

Was this visit performed? Yes ☒  
No ☐

Visit date (dd MMM yyyy) 03 MAR 2021

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

Folder OID UNBLND\_DECIDE



US3812081

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 20:56:40

Generated On: 10 Jun 2021 09:54:48

Date of updated informed consent (dd MMM yyyy) 03 MAR 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 03 MAR 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3812081

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 20:56:40

Generated On: 10 Jun 2021 09:54:48

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 03 MAR 2021

Collection time (00:00-23:59) 16:10 (24 HR)

Collection date and time (derived) 03 MAR 2021 16:10

US3812081

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Mar 2021 20:56:40

Generated On: 10 Jun 2021 09:54:48

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 03 MAR 2021

Collection time (00:00 - 23:59) 16:15

Collection Date and Time (derived) 03 MAR 2021 16:15

US3812081

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 08 Apr 2021 00:48:59

Generated On: 10 Jun 2021 09:54:48

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3812081

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:54:48

AEID	USA-US111-2021-MRNA-1273-P30 1000014
Adverse event	ACUTE APPENDICITIS
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)	29 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	01 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	31 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	01 APR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3812081

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:54:48

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <input type="radio"/>
	Withdrawn <input type="radio"/>
	Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/>
	Not Recovered/Not Resolved <input type="radio"/>
	Recovered/Resolved <input checked="" type="radio"/>
	Recovered/Resolved with Sequelae <input type="radio"/>
	Recovering/Resolving <input type="radio"/>
	Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

**US3812081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Data signed:** (b) (4) **30 Apr 2021 02:45:27**

**Generated On: 10 Jun 2021 09:54:48**

---

SUBJECT US3812081 IS A  
48-YEAR-OLD MALE WITH A  
PAST MEDICAL HISTORY OF  
HYPERLIPIDEMIA  
WHO PRESENTED TO THE  
EMERGENCY DEPARTMENT ON  
31 MAR 2021 WITH A CHIEF  
COMPLAINT OF RIGHT LOWER  
ABDOMINAL PAIN FOR 2 DAYS,  
NAUSEA, AND FEVER.  
FINDINGS FROM THE CT SCAN  
OF ABDOMEN AND PELVIS  
WERE CONSISTENT WITH  
ACUTE APPENDICITIS  
WITHOUT PERFORATION.  
SUBJECT UNDERWENT AN  
URGENT LAPAROSCOPIC  
APPENDECTOMY THAT SAME  
DAY AND WAS KEPT  
OVERNIGHT FOR  
POST-OPERATIVE  
OBSERVATION. LABS  
OBTAINED THROUGHOUT  
HOSPITALIZATION WERE  
UNREMARKABLE AND THE  
SUBJECT'S POST-OPERATIVE  
PAIN WAS WELL-CONTROLLED.  
SUBJECT WAS DISCHARGED ON  
01 APRIL 2021 IN STABLE  
CONDITION WITH THE  
FOLLOWING DISCHARGE  
MEDICATIONS: SENOKOT-S  
8.6-50 MG 2 TABLETS PO HS  
AND  
HYDROCODONE/ACETAMINOP

US3812081

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 02:45:27

Generated On: 10 Jun 2021 09:54:48

---

HEN 5-325 MG 1 TABLET PO Q  
4-6 HOURS PRN.  
HOSPITALIZATION RECORDS  
WERE RECONCILED WITH THE  
SUBJECT ON 15 APR 2021.  
SUBJECT DENIED TAKING ANY  
OF HIS PRESCRIBED  
DISCHARGE MEDICATIONS  
AND REPORTED COMPLETE  
RESOLUTION OF HIS  
ABDOMINAL PAIN. SUBJECT  
DENIED HAVING ANY  
POST-OPERATIVE  
COMPLICATIONS.

---

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

---



US3812081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Mar 2021 20:56:40

Generated On: 10 Jun 2021 09:54:48

---

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

---

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

---

US3812081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Apr 2021 14:41:21

Generated On: 10 Jun 2021 09:54:48

Name of Medication VITAMIN D

Prophylaxis Yes ☒  
No ☐

Indication GENERAL HEALTH

Dose per administration 50,000

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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EAB) (1725)

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US3812081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 21 Apr 2021 14:41:21

Generated On: 10 Jun 2021 09:54:48

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	04 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3812081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Apr 2021 14:41:21

Generated On: 10 Jun 2021 09:54:48

Name of Medication FLU VACCINE

Prophylaxis Yes ☒  
No ☐

Indication FLU 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 ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3812081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 21 Apr 2021 14:41:21

Generated On: 10 Jun 2021 09:54:48

	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)		07 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)		07 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"/>

US3812081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 08 Apr 2021 00:48:59

Generated On: 10 Jun 2021 09:54:48

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3812081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 14 Apr 2021 21:54:35

Generated On: 10 Jun 2021 09:54:48

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
01 APR 2021	LAPAROSCOPIC APPENDECTOMY	Adverse Event	
31 MAR 2021	CT SCAN OF THE ABDOMEN AND PELVIS	Adverse Event	

US3812081

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:54:48

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



US3812081

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:54:48

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 ☐

US3812081

Folder: SAE USA-US111-2021-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 01 May 2021 20:47:47

Generated On: 10 Jun 2021 09:54:48

SAEID	USA-US111-2021-MRNA-1273-P301000014
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3812081

Folder: SAE USA-US111-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 01 May 2021 20:47:47

Generated On: 10 Jun 2021 09:54:48

SAEID	USA-US111-2021-MRNA-1273-P301000014
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	05/APR/2021 09:30
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3812081

Folder: SAE USA-US111-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Data signed: (b) (4) 01 May 2021 20:47:47

Generated On: 10 Jun 2021 09:54:48

SAEID	USA-US111-2021-MRNA-1273-P301000014
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	15/APR/2021 11:36
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

US3812081

Folder: SAE USA-US111-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Data signed: (b) (4) 01 May 2021 20:47:47

Generated On: 10 Jun 2021 09:54:48

SAEID	USA-US111-2021-MRNA-1273-P301000014
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	21/APR/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

US3812081

Folder: SAE USA-US111-2021-MRNA-1273-P301000014

Form: Safety Report Form (4)

Data signed: (b) (4) 01 May 2021 20:47:47

Generated On: 10 Jun 2021 09:54:48

SAEID	USA-US111-2021-MRNA-1273-P301000014
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	26/APR/2021 13:03
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

US3812081

Folder: SAE USA-US111-2021-MRNA-1273-P301000014

Form: Safety Report Form (5)

Data signed: (b) (4) 01 May 2021 20:47:47

Generated On: 10 Jun 2021 09:54:48

SAEID	USA-US111-2021-MRNA-1273-P301000014
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	LAUREN
Investigator's Last Name	CLEMENT
Site Address: Street	
Site Address: City	
Site Address: State	MO
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	30/APR/2021 10:27
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

US3812081 (Prod: Sundance Clinical Research - Platinum - PPDS)



**US3812081**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:54:48**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'US3812081'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 21:54:15

**US3812081**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:54:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 22:18:38

**US3812081**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:54:48**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '07 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 21:54:16

**US3812081**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:54:48**

[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 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	07 Aug 2020 22:18:38

**US3812081**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:54:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered 'SCRN'	System	07 Aug 2020 22:18:38

**US3812081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:54:48**

[Date of Birth \(MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered (b) (6) 1972'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 21:54:17

**US3812081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:54:48**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '47'	Breanna Galibert (b) (4)	07 Aug 2020 22:52:02

**US3812081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:54:48**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered 'YEARS'	System	07 Aug 2020 22:52:02



**US3812081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:54:48**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered '47'	System	07 Aug 2020 22:18:49

**US3812081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:54:48**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Male (M)'	Breanna Galibert (b) (4)	07 Aug 2020 22:52:02

**US3812081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:54:48**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Breanna Galibert (b) (4)	07 Aug 2020 22:52:02

**US3812081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:54:48**

**White**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'I'	Breanna Galibert (b) (4)	07 Aug 2020 22:52:02

**US3812081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:54:48**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 22:52:02

**US3812081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:54:48**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 22:52:02

**US3812081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:54:48**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 22:52:02

**US3812081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:54:48**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 22:52:02



**US3812081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:54:48**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 22:52:02

**US3812081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:54:48**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 22:52:02

**US3812081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:54:48**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 22:52:02

**US3812081**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:54:48**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Breanna Galibert (b) (4)	07 Aug 2020 22:52:02

US3812081

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:54:48

[Date of Informed Consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '7 Aug 2020'	Breanna Galibert (b) (4)	07 Aug 2020 22:18:49

**US3812081**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:54:48**

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered 'Aug 2020'	System	07 Aug 2020 22:18:49

**US3812081**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:54:48**

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered '2020'	System	07 Aug 2020 22:18:49

**US3812081**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:54:48**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Amendment 1 (1)'	Breanna Galibert (b) (4)	07 Aug 2020 22:18:49



**US3812081**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:54:48**

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 22:18:49

**US3812081**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:54:48**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 22:18:49

**US3812081**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:54:48**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 22:18:49

**US3812081**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:54:48**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'No (N)'	Breanna Galibert (b) (4)	07 Aug 2020 22:18:49

**US3812081**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:54:48**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 21:54:16

US3812081

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:54:48

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered 'I'	System	07 Aug 2020 22:18:53

US3812081

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:54:48

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 22:18:53

**US3812081**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:54:48**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 17:35:56



US3812081

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:54:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Visual impairment and blindness (excl colour blindness), PT: Visual impairment, LLT: Visual impairment - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 17:38:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 17:38:17
Data point term sent to Coder	System	10 Aug 2020 17:36:49
User entered 'BILATERAL VISUAL IMPAIRMENT'	Breanna Galibert (b) (4)	10 Aug 2020 17:36:25

**US3812081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'UN UNK 1987'	Breanna Galibert (b) (4)	10 Aug 2020 17:36:25

**US3812081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Breanna Galibert (b) (4)	10 Aug 2020 17:36:25

**US3812081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 17:36:25

**US3812081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:54:48**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 17:36:25

**US3812081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Breanna Galibert (b) (4)	10 Aug 2020 17:36:25

**US3812081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered 'Jan 1987'	System	10 Aug 2020 17:36:25

**US3812081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered '1987'	System	10 Aug 2020 17:36:25



**US3812081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered empty.	System	10 Aug 2020 17:36:25

**US3812081**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered empty.	System	10 Aug 2020 17:36:25

US3812081

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:54:48

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 17:38:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	10 Aug 2020 17:38:16
Data point term sent to Coder	System	10 Aug 2020 17:37:52
User entered 'SEASONAL ALLERGIES'	Breanna Galibert (b) (4)	10 Aug 2020 17:37:22

**US3812081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'UN UNK 1995'	Breanna Galibert (b) (4)	10 Aug 2020 17:37:22

**US3812081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Breanna Galibert (b) (4)	10 Aug 2020 17:37:22

**US3812081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 17:37:22

**US3812081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:54:48**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 17:37:22

**US3812081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Breanna Galibert (b) (4)	10 Aug 2020 17:37:22



**US3812081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered 'Jan 1995'	System	10 Aug 2020 17:37:22

**US3812081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered '1995'	System	10 Aug 2020 17:37:22

**US3812081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered empty.	System	10 Aug 2020 17:37:22

**US3812081**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered empty.	System	10 Aug 2020 17:37:22

US3812081

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:54:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 13:41:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 13:41:19
Data point term sent to Coder	System	14 Aug 2020 13:39:48
User entered 'Hyperlipidemia'	Megan Dandurand (b) (4)	14 Aug 2020 13:39:39

**US3812081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:54:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '18 Oct 2017'	Megan Dandurand (b) (4)	14 Aug 2020 13:39:39

**US3812081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:54:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Megan Dandurand (b) (4)	14 Aug 2020 13:39:39

**US3812081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:54:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Megan Dandurand (b) (4)	14 Aug 2020 13:39:39



**US3812081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:54:48**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Megan Dandurand (b) (4)	14 Aug 2020 13:39:39

**US3812081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:54:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Megan Dandurand (b) (4)	14 Aug 2020 13:39:39

**US3812081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:54:48**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered 'Oct 2017'	System	14 Aug 2020 13:39:39

**US3812081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:54:48**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered '2017'	System	14 Aug 2020 13:39:39

**US3812081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:54:48**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered empty.	System	14 Aug 2020 13:39:39

**US3812081**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:54:48**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered empty.	System	14 Aug 2020 13:39:39

US3812081

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:54:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Vitamin related disorders, HLT: Fat soluble vitamin deficiencies and disorders, PT: Vitamin D deficiency, LLT: Vitamin D deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 13:41:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 13:41:20
Data point term sent to Coder	System	14 Aug 2020 13:40:49
User entered 'Vitamin D Deficiency'	Megan Dandurand (b) (4)	14 Aug 2020 13:40:18

**US3812081**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:54:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '18 Oct 2017'	Megan Dandurand (b) (4)	14 Aug 2020 13:40:18



**US3812081**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:54:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Megan Dandurand (b) (4)	14 Aug 2020 13:40:18

**US3812081**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:54:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Megan Dandurand (b) (4)	14 Aug 2020 13:40:18

**US3812081**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:54:48**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Megan Dandurand (b) (4)	14 Aug 2020 13:40:18

**US3812081**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:54:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Megan Dandurand (b) (4)	14 Aug 2020 13:40:18

**US3812081**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:54:48**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered 'Oct 2017'	System	14 Aug 2020 13:40:18

**US3812081**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:54:48**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered '2017'	System	14 Aug 2020 13:40:18

**US3812081**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:54:48**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered empty.	System	14 Aug 2020 13:40:18

**US3812081**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:54:48**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered empty.	System	14 Aug 2020 13:40:18



US3812081

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:54:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Lipid metabolism and deposit disorders NEC, PT: Lipoprotein deficiency, LLT: Lipoprotein deficiency - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 10:46:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 10:46:09
Data point term sent to Coder	System	14 Aug 2020 13:40:50
User entered 'Lipoprotein Deficiency Disorder'	Megan Dandurand (b) (4)	14 Aug 2020 13:40:43

**US3812081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:54:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '18 Oct 2017'	Megan Dandurand (b) (4)	14 Aug 2020 13:40:43

**US3812081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:54:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Megan Dandurand (b) (4)	14 Aug 2020 13:40:43

**US3812081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:54:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Megan Dandurand (b) (4)	14 Aug 2020 13:40:43

**US3812081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:54:48**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Megan Dandurand (b) (4)	14 Aug 2020 13:40:43

**US3812081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:54:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Megan Dandurand (b) (4)	14 Aug 2020 13:40:43

**US3812081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:54:48**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered 'Oct 2017'	System	14 Aug 2020 13:40:43

**US3812081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:54:48**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered '2017'	System	14 Aug 2020 13:40:43



**US3812081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:54:48**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered empty.	System	14 Aug 2020 13:40:43

**US3812081**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:54:48**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered empty.	System	14 Aug 2020 13:40:43

US3812081

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:54:48

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Dyspeptic signs and symptoms, PT: Dyspepsia, LLT: Indigestion - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 16:27:21
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	14 Aug 2020 16:27:21
Data point term sent to Coder	System	14 Aug 2020 13:41:50
User entered 'Frequent Indigestion'	Megan Dandurand (b) (4)	14 Aug 2020 13:41:12

**US3812081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:54:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'un UNK 2019'	Megan Dandurand (b) (4)	14 Aug 2020 13:41:12

**US3812081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:54:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Megan Dandurand (b) (4)	14 Aug 2020 13:41:12

**US3812081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:54:48**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Megan Dandurand (b) (4)	14 Aug 2020 13:41:12

**US3812081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:54:48**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Megan Dandurand (b) (4)	14 Aug 2020 13:41:12

**US3812081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:54:48**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Megan Dandurand (b) (4)	14 Aug 2020 13:41:12



**US3812081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:54:48**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered 'Jan 2019'	System	14 Aug 2020 13:41:12

**US3812081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:54:48**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered '2019'	System	14 Aug 2020 13:41:12

**US3812081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:54:48**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered empty.	System	14 Aug 2020 13:41:12

**US3812081**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:54:48**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered empty.	System	14 Aug 2020 13:41:12

US3812081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:05

**US3812081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '7 Aug 2020'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:05

**US3812081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '16:16'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:05

**US3812081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered '7 Aug 2020 16:16'	System	10 Aug 2020 17:39:05



**US3812081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '72.5' in	Breanna Galibert (b) (4)	10 Aug 2020 17:39:05
DataPoint set to visible.	System	07 Aug 2020 22:18:53

US3812081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '233.0' lb	Breanna Galibert (b) (4)	10 Aug 2020 17:39:05
DataPoint set to visible.	System	07 Aug 2020 22:18:53

**US3812081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
Amendment Manager: User entered '31.23128'	System	16 Sep 2020 23:48:24
User entered '31.2'	System	10 Aug 2020 17:39:05
DataPoint set to visible.	System	07 Aug 2020 22:18:53

**US3812081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered 'kg/m2'	System	10 Aug 2020 17:39:05
DataPoint set to visible.	System	07 Aug 2020 22:18:53

US3812081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 17:39:05

US3812081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Other (Other)'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:05

**US3812081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 17:39:05

**US3812081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 17:39:05



**US3812081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered 'bpm'	System	10 Aug 2020 17:39:05

US3812081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 17:39:05

**US3812081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered 'breaths/min'	System	10 Aug 2020 17:39:05

**US3812081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 17:39:05

**US3812081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered 'mmHg'	System	10 Aug 2020 17:39:05

**US3812081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 17:39:05

**US3812081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User entered 'mmHg'	System	10 Aug 2020 17:39:05

**US3812081**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23



US3812081

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23

**US3812081**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:54:48**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:13

US3812081

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 10:59:13
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	02 Sep 2020 22:45:27
User entered '7 Aug 2020'	Breanna Galibert (b) (4) (b) (4)	10 Aug 2020 17:39:13

US3812081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:48

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:47

US3812081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:48

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:47

US3812081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:48

**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)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:47

US3812081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:48

**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)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:47

US3812081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:48

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:47



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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:48

[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)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:47

US3812081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:48

**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)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:47

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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:48

**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)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:47

US3812081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:48

[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)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:47

US3812081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:48

**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)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:47

US3812081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:48

**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)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:47

**US3812081**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:54:48**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:47

US3812081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 17:39:47



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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)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'I'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:47

US3812081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:48

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:47

US3812081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:48

**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)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:47

US3812081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:48

[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)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:47

US3812081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:48

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)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:47

US3812081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:48

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:47

**US3812081**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:54:48**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '0'	Breanna Galibert (b) (4)	10 Aug 2020 17:39:47

US3812081

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:54:48

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:14:23
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 17:39:47



**US3812081**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:54:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 22:19:02

**US3812081**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:54:48**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '7 Aug 2020'	Breanna Galibert (b) (4)	07 Aug 2020 22:19:02

US3812081

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:54:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	07 Aug 2020 22:19:02

**US3812081**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:54:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User entered 'VISIT1'	System	07 Aug 2020 22:19:02

US3812081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '07 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 21:54:20

US3812081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:54:48

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 03:02:21
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:02:21
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	07 Aug 2020 21:54:20
User entered '102252' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 21:54:20

US3812081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:54:48

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	07 Aug 2020 21:54:20

US3812081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:54:48

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)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 17:40:06



US3812081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:54:48

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)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 17:40:06

US3812081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:54:48

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 17:40:06

**US3812081**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:54:48**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 17:40:06

US3812081

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:54:48

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 17:40:06

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:54:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:54:48

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:54:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:54:48

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30



US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4) (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '7 Aug 2020'	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '16:16'	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User entered '7 Aug 2020 16:16'	System	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '97.1' F	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30



US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '60'	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User entered 'bpm'	System	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '14'	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User entered 'breaths/min'	System	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '126'	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User entered 'mmHg'	System	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '86'	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User entered 'mmHg'	System	10 Aug 2020 17:41:30



US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:54:48

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:54:48

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4) (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '7 Aug 2020'	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 13:33:06
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		10 Aug 2020 17:41:30
User entered '17:43'	Breanna Galibert (b) (4) (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User entered '7 Aug 2020 17:43'	System	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '97.0' F	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30



US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

**US3812081**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '58'	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

**US3812081**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User entered 'bpm'	System	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '14'	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User entered 'breaths/min'	System	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '134'	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User entered 'mmHg'	System	10 Aug 2020 17:41:30



US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '88'	Breanna Galibert (b) (4)	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User entered 'mmHg'	System	10 Aug 2020 17:41:30

US3812081

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 17:41:36

US3812081

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 17:41:36

US3812081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:54:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	07 Aug 2020 22:19:27

US3812081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:54:48

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 22:19:27

US3812081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:54:48

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)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Breanna Galibert (b) (4)	07 Aug 2020 22:19:27

**US3812081**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:54:48**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User entered 'MRNA-1273 OR PLACEBO'	System	07 Aug 2020 22:19:27



US3812081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:54:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '7 Aug 2020'	Breanna Galibert (b) (4)	07 Aug 2020 22:19:27

US3812081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:54:48

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '17:12'	Breanna Galibert (b) (4)	07 Aug 2020 22:19:27

**US3812081**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:54:48**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User entered '7 Aug 2020 17:12'	System	07 Aug 2020 22:19:27

US3812081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:54:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Left Arm (LEFT ARM)'	Breanna Galibert (b) (4)	07 Aug 2020 22:19:27

US3812081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:54:48

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User entered 'ONCE'	System	07 Aug 2020 22:19:27

US3812081

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:54:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User entered 'INTRAMUSCULAR'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:54:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 17:41:57

US3812081

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '7 Aug 2020'	Breanna Galibert (b) (4)	10 Aug 2020 17:41:57



**US3812081**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:54:48**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '17:07'	Breanna Galibert (b) (4)	10 Aug 2020 17:41:57

**US3812081**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:54:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User entered '7 Aug 2020 17:07'	System	10 Aug 2020 17:41:57

US3812081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:54:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '7 Aug 2020'	Breanna Galibert (b) (4)	10 Aug 2020 17:42:10

**US3812081**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Breanna Galibert (b) (4) (b) (4)	10 Aug 2020 17:42:10

US3812081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:54:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 17:42:10

**US3812081**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:54:48**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '17:09'	Breanna Galibert (b) (4)	10 Aug 2020 17:42:10

**US3812081**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User entered '7 Aug 2020 17:09'	System	10 Aug 2020 17:42:10

**US3812081**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Breanna Galibert (b) (4)	10 Aug 2020 17:42:10



US3812081

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:54:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 17:42:10

**US3812081**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 17:42:10

**US3812081**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User entered empty.	System	10 Aug 2020 17:42:10

**US3812081**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:54:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	18 Aug 2020 17:11:13

**US3812081**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:54:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User entered '1'	System	18 Aug 2020 17:11:13

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T17:47:30', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '4042c995-d824-4d91-97be-ad12401cd968'	System	07 Aug 2020 22:47:49
User entered 'Yes (Y)'	System	07 Aug 2020 22:47:49

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T17:47:36', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '4042c995-d824-4d91-97be-ad12401cd968'	System	07 Aug 2020 22:47:49
User entered '97.0'	System	07 Aug 2020 22:47:49



US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T17:47:43', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '4042c995-d824-4d91-97be-ad12401cd968'	System	07 Aug 2020 22:47:49
User entered 'No (N)'	System	07 Aug 2020 22:47:49

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T17:47:47', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '4042c995-d824-4d91-97be-ad12401cd968'	System	07 Aug 2020 22:47:49
User entered '07 Aug 2020 17:47'	System	07 Aug 2020 22:47:49

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '07 Aug 2020 17:32'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '07 Aug 2020 20:02'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:54:48**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T22:28:38', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c42b818f-d1a5-43ae-a473-39cf9d2e436d' User entered 'Yes (Y)'	System	08 Aug 2020 03:28:57
	System	08 Aug 2020 03:28:57

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T22:28:46', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c42b818f-d1a5-43ae-a473-39cf9d2e436d' User entered '97.0'	System	08 Aug 2020 03:28:57
	System	08 Aug 2020 03:28:57

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T22:28:51', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c42b818f-d1a5-43ae-a473-39cf9d2e436d' User entered 'No (N)'	System	08 Aug 2020 03:28:57
	System	08 Aug 2020 03:28:57



**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T22:28:56', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c42b818f-d1a5-43ae-a473-39cf9d2e436d' User entered '07 Aug 2020 22:28'	System	08 Aug 2020 03:28:57
	System	08 Aug 2020 03:28:57

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '07 Aug 2020 20:57'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 2'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-08T21:20:29', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '1d3c66e5-acfa-41da-b635-4cb50ec4492f' User entered 'Yes (Y)'	System	09 Aug 2020 02:20:55
	System	09 Aug 2020 02:20:55

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-08T21:20:35', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '1d3c66e5-acfa-41da-b635-4cb50ec4492f' User entered '98.0'	System	09 Aug 2020 02:20:55
	System	09 Aug 2020 02:20:55

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-08T21:20:39', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '1d3c66e5-acfa-41da-b635-4cb50ec4492f' User entered 'No (N)'	System	09 Aug 2020 02:20:55
	System	09 Aug 2020 02:20:55

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-08T21:20:43', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '1d3c66e5-acfa-41da-b635-4cb50ec4492f' User entered '08 Aug 2020 21:20'	System	09 Aug 2020 02:20:55
	System	09 Aug 2020 02:20:55



US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 3'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-09T19:24:34', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '8c6d2149-12ba-4ee8-a1bd-ef56ffdb2937'	System	10 Aug 2020 00:26:11
User entered 'Yes (Y)'	System	10 Aug 2020 00:26:11

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-09T19:25:58', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '8c6d2149-12ba-4ee8-a1bd-ef56ffdb2937'	System	10 Aug 2020 00:26:11
User entered '97.5'	System	10 Aug 2020 00:26:11

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-09T19:26:05', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '8c6d2149-12ba-4ee8-a1bd-ef56ffdb2937'	System	10 Aug 2020 00:26:11
User entered 'No (N)'	System	10 Aug 2020 00:26:11

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-09T19:26:08', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '8c6d2149-12ba-4ee8-a1bd-ef56ffdb2937'	System	10 Aug 2020 00:26:11
User entered '09 Aug 2020 19:26'	System	10 Aug 2020 00:26:11

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 22:19:27



US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 4'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-10T19:25:58', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c98c43a3-5703-4f26-a38a-e7cffe0cd9d'	System	11 Aug 2020 00:26:17
User entered 'Yes (Y)'	System	11 Aug 2020 00:26:17

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-10T19:26:03', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c98c43a3-5703-4f26-a38a-e7cffe0cd9d'	System	11 Aug 2020 00:26:17
User entered '97.2'	System	11 Aug 2020 00:26:17

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-10T19:26:09', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c98c43a3-5703-4f26-a38a-e7cffe0cd9d'	System	11 Aug 2020 00:26:17
User entered 'No (N)'	System	11 Aug 2020 00:26:17

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-10T19:26:14', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c98c43a3-5703-4f26-a38a-e7cffe0cd9d'	System	11 Aug 2020 00:26:17
User entered '10 Aug 2020 19:26'	System	11 Aug 2020 00:26:17

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 22:19:27



US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 5'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T05:53:51', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'bb0890bc-9bf9-42fd-bdc8-3014522e5d9b'	System	12 Aug 2020 10:54:13
User entered 'Yes (Y)'	System	12 Aug 2020 10:54:13

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T05:54:01', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'bb0890bc-9bf9-42fd-bdc8-3014522e5d9b' User entered '96.8'	System	12 Aug 2020 10:54:13
	System	12 Aug 2020 10:54:13

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T05:54:05', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'bb0890bc-9bf9-42fd-bdc8-3014522e5d9b'	System	12 Aug 2020 10:54:13
User entered 'No (N)'	System	12 Aug 2020 10:54:13

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T05:54:09', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'bb0890bc-9bf9-42fd-bdc8-3014522e5d9b' User entered '12 Aug 2020 05:54'	System	12 Aug 2020 10:54:13
	System	12 Aug 2020 10:54:13

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 6'	System	07 Aug 2020 22:19:27



US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T19:09:01', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '122c371b-4658-43cb-9c85-64e3475c9a39'	System	13 Aug 2020 00:09:19
User entered 'Yes (Y)'	System	13 Aug 2020 00:09:19

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T19:09:08', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '122c371b-4658-43cb-9c85-64e3475c9a39' User entered '97.7'	System	13 Aug 2020 00:09:19
	System	13 Aug 2020 00:09:19

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T19:09:12', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '122c371b-4658-43cb-9c85-64e3475c9a39'	System	13 Aug 2020 00:09:19
User entered 'No (N)'	System	13 Aug 2020 00:09:19

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T19:09:15', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '122c371b-4658-43cb-9c85-64e3475c9a39'	System	13 Aug 2020 00:09:19
User entered '12 Aug 2020 19:09'	System	13 Aug 2020 00:09:19

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 7'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-13T21:17:18', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'dcab99f3-f5c2-4bbb-abc1-98be45fd14b8' User entered 'Yes (Y)'	System	14 Aug 2020 02:18:08
	System	14 Aug 2020 02:18:08



US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-13T21:17:57', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'dcab99f3-f5c2-4bbb-abc1-98be45fd14b8' User entered '97.3'	System	14 Aug 2020 02:18:08
	System	14 Aug 2020 02:18:08

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-13T21:18:01', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'dcab99f3-f5c2-4bbb-abc1-98be45fd14b8'	System	14 Aug 2020 02:18:08
User entered 'No (N)'	System	14 Aug 2020 02:18:08

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-13T21:18:04', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'dcab99f3-f5c2-4bbb-abc1-98be45fd14b8'	System	14 Aug 2020 02:18:08
User entered '13 Aug 2020 21:18'	System	14 Aug 2020 02:18:08

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T17:47:54', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '429a49e2-05d3-4714-8f94-e4f7ca423f4e' User entered 'None (1)'	System	07 Aug 2020 22:48:10
	System	07 Aug 2020 22:48:10

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T17:47:57', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '429a49e2-05d3-4714-8f94-e4f7ca423f4e'	System	07 Aug 2020 22:48:10
User entered 'No (N)'	System	07 Aug 2020 22:48:10



US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T17:48:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '429a49e2-05d3-4714-8f94-e4f7ca423f4e' User entered 'No (N)'	System	07 Aug 2020 22:48:10
	System	07 Aug 2020 22:48:10

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T17:48:04', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '429a49e2-05d3-4714-8f94-e4f7ca423f4e'	System	07 Aug 2020 22:48:10
User entered 'None (1)'	System	07 Aug 2020 22:48:10

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T17:48:07', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '429a49e2-05d3-4714-8f94-e4f7ca423f4e' User entered '07 Aug 2020 17:48'	System	07 Aug 2020 22:48:10
	System	07 Aug 2020 22:48:10

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '07 Aug 2020 17:32'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '07 Aug 2020 20:02'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T22:29:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '8fd68d2e-cdc0-4f58-b8e6-369ffdd1aac3'	System	08 Aug 2020 03:29:14
User entered 'None (1)'	System	08 Aug 2020 03:29:14

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T22:29:03', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '8fd68d2e-cdc0-4f58-b8e6-369ffdd1aac3'	System	08 Aug 2020 03:29:14
User entered 'No (N)'	System	08 Aug 2020 03:29:14



US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T22:29:05', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '8fd68d2e-cdc0-4f58-b8e6-369ffdd1aac3' User entered 'No (N)'	System	08 Aug 2020 03:29:14
	System	08 Aug 2020 03:29:14

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T22:29:09', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '8fd68d2e-cdc0-4f58-b8e6-369ffdd1aac3'	System	08 Aug 2020 03:29:14
User entered 'None (1)'	System	08 Aug 2020 03:29:14

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T22:29:13', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '8fd68d2e-cdc0-4f58-b8e6-369ffdd1aac3' User entered '07 Aug 2020 22:29'	System	08 Aug 2020 03:29:14
	System	08 Aug 2020 03:29:14

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '07 Aug 2020 20:57'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 2'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-08T21:21:15', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f3454977-4fac-4d4e-bf5d-f705ad78a6ff'	System	09 Aug 2020 02:24:12
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 02:24:12

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:54:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-08T21:21:19', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f3454977-4fac-4d4e-bf5d-f705ad78a6ff' User entered 'Yes (Y)'	System	09 Aug 2020 02:24:12
	System	09 Aug 2020 02:24:12



US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:54:48

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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-08T21:23:47', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f3454977-4fac-4d4e-bf5d-f705ad78a6ff' User entered '25'	System	09 Aug 2020 02:24:12
	System	09 Aug 2020 02:24:12

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-08T21:23:42', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f3454977-4fac-4d4e-bf5d-f705ad78a6ff'	System	09 Aug 2020 02:24:12
User entered 'No (N)'	System	09 Aug 2020 02:24:12

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-08T21:24:01', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f3454977-4fac-4d4e-bf5d-f705ad78a6ff' User entered 'None (1)'	System	09 Aug 2020 02:24:12
	System	09 Aug 2020 02:24:12

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-08T21:24:06', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f3454977-4fac-4d4e-bf5d-f705ad78a6ff' User entered '08 Aug 2020 21:24'	System	09 Aug 2020 02:24:12
	System	09 Aug 2020 02:24:12

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 3'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-09T19:26:13', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '28c8c937-614f-4c2a-8a54-96d7eb39e1c5'	System	10 Aug 2020 00:26:28
User entered 'None (1)'	System	10 Aug 2020 00:26:28



US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:54:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-09T19:26:16', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '28c8c937-614f-4c2a-8a54-96d7eb39e1c5'	System	10 Aug 2020 00:26:28
User entered 'No (N)'	System	10 Aug 2020 00:26:28

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-09T19:26:19', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '28c8c937-614f-4c2a-8a54-96d7eb39e1c5'	System	10 Aug 2020 00:26:28
User entered 'No (N)'	System	10 Aug 2020 00:26:28

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-09T19:26:22', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '28c8c937-614f-4c2a-8a54-96d7eb39e1c5'	System	10 Aug 2020 00:26:28
User entered 'None (1)'	System	10 Aug 2020 00:26:28

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-09T19:26:25', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '28c8c937-614f-4c2a-8a54-96d7eb39e1c5' User entered '09 Aug 2020 19:26'	System	10 Aug 2020 00:26:28
	System	10 Aug 2020 00:26:28

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 4'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-10T19:26:18', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'a8cab49e-638f-4df1-bf5e-e4c5d3fd56df'	System	11 Aug 2020 00:26:31
User entered 'None (1)'	System	11 Aug 2020 00:26:31



US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:54:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-10T19:26:20', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'a8cab49e-638f-4df1-bf5e-e4c5d3fd56df'	System	11 Aug 2020 00:26:31
User entered 'No (N)'	System	11 Aug 2020 00:26:31

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-10T19:26:23', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'a8cab49e-638f-4df1-bf5e-e4c5d3fd56df' User entered 'No (N)'	System	11 Aug 2020 00:26:31
	System	11 Aug 2020 00:26:31

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-10T19:26:25', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'a8cab49e-638f-4df1-bf5e-e4c5d3fd56df'	System	11 Aug 2020 00:26:31
User entered 'None (1)'	System	11 Aug 2020 00:26:31

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-10T19:26:28', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'a8cab49e-638f-4df1-bf5e-e4c5d3fd56df' User entered '10 Aug 2020 19:26'	System	11 Aug 2020 00:26:31
	System	11 Aug 2020 00:26:31

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 5'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T05:54:15', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '97216b91-5893-4b31-9041-5bfdee41cd99'	System	12 Aug 2020 10:54:29
User entered 'None (1)'	System	12 Aug 2020 10:54:29



US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:54:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T05:54:18', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '97216b91-5893-4b31-9041-5bfdee41cd99'	System	12 Aug 2020 10:54:29
User entered 'No (N)'	System	12 Aug 2020 10:54:29

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T05:54:21', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '97216b91-5893-4b31-9041-5bfdee41cd99'	System	12 Aug 2020 10:54:29
User entered 'No (N)'	System	12 Aug 2020 10:54:29

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T05:54:25', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '97216b91-5893-4b31-9041-5bfdee41cd99'	System	12 Aug 2020 10:54:29
User entered 'None (1)'	System	12 Aug 2020 10:54:29

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T05:54:27', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '97216b91-5893-4b31-9041-5bfdee41cd99' User entered '12 Aug 2020 05:54'	System	12 Aug 2020 10:54:29
	System	12 Aug 2020 10:54:29

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 6'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T19:09:21', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '34ecd579-19e2-4fa9-baf5-31c1fb136192'	System	13 Aug 2020 00:09:35
User entered 'None (1)'	System	13 Aug 2020 00:09:35



US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:54:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T19:09:24', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '34ecd579-19e2-4fa9-baf5-31c1fb136192'	System	13 Aug 2020 00:09:35
User entered 'No (N)'	System	13 Aug 2020 00:09:35

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T19:09:27', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '34ecd579-19e2-4fa9-baf5-31c1fb136192'	System	13 Aug 2020 00:09:35
User entered 'No (N)'	System	13 Aug 2020 00:09:35

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T19:09:29', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '34ecd579-19e2-4fa9-baf5-31c1fb136192'	System	13 Aug 2020 00:09:35
User entered 'None (1)'	System	13 Aug 2020 00:09:35

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T19:09:31', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '34ecd579-19e2-4fa9-baf5-31c1fb136192'	System	13 Aug 2020 00:09:35
User entered '12 Aug 2020 19:09'	System	13 Aug 2020 00:09:35

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 7'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-13T21:18:09', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '4dd6c78e-4cbf-468f-9d6d-5c47afd20523'	System	14 Aug 2020 02:18:26
User entered 'None (1)'	System	14 Aug 2020 02:18:26



US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:54:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-13T21:18:12', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '4dd6c78e-4cbf-468f-9d6d-5c47afd20523'	System	14 Aug 2020 02:18:26
User entered 'No (N)'	System	14 Aug 2020 02:18:26

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-13T21:18:15', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '4dd6c78e-4cbf-468f-9d6d-5c47afd20523'	System	14 Aug 2020 02:18:26
User entered 'No (N)'	System	14 Aug 2020 02:18:26

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-13T21:18:19', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '4dd6c78e-4cbf-468f-9d6d-5c47afd20523'	System	14 Aug 2020 02:18:26
User entered 'None (1)'	System	14 Aug 2020 02:18:26

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-13T21:18:22', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '4dd6c78e-4cbf-468f-9d6d-5c47afd20523'	System	14 Aug 2020 02:18:26
User entered '13 Aug 2020 21:18'	System	14 Aug 2020 02:18:26

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:54:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T17:48:13', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'fad4f20f-5385-4550-8248-a89ad45189e6' User entered 'None (0)'	System	07 Aug 2020 22:48:43
	System	07 Aug 2020 22:48:43



**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:54:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T17:48:17', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'fad4f20f-5385-4550-8248-a89ad45189e6' User entered 'None (0)'	System	07 Aug 2020 22:48:43
	System	07 Aug 2020 22:48:43

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T17:48:19', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'fad4f20f-5385-4550-8248-a89ad45189e6' User entered 'None (0)'	System	07 Aug 2020 22:48:43
	System	07 Aug 2020 22:48:43

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T17:48:24', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'fad4f20f-5385-4550-8248-a89ad45189e6' User entered 'None (0)'	System	07 Aug 2020 22:48:43
	System	07 Aug 2020 22:48:43

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T17:48:29', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'fad4f20f-5385-4550-8248-a89ad45189e6' User entered 'None (0)'	System	07 Aug 2020 22:48:43
	System	07 Aug 2020 22:48:43

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:54:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T17:48:33', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'fad4f20f-5385-4550-8248-a89ad45189e6' User entered 'None (0)'	System	07 Aug 2020 22:48:43
	System	07 Aug 2020 22:48:43

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T17:48:39', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'fad4f20f-5385-4550-8248-a89ad45189e6'	System	07 Aug 2020 22:48:43
User entered 'No (N)'	System	07 Aug 2020 22:48:43

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T17:48:41', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'fad4f20f-5385-4550-8248-a89ad45189e6'	System	07 Aug 2020 22:48:43
User entered '07 Aug 2020 17:48'	System	07 Aug 2020 22:48:43

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '07 Aug 2020 17:32'	System	07 Aug 2020 22:19:27



US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '07 Aug 2020 20:02'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 1, after vaccination (at home)'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T22:29:17', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'dbd85a34-6ac8-4a82-8ea9-e05ba8ca90a1' User entered 'None (0)'	System	08 Aug 2020 03:29:35
	System	08 Aug 2020 03:29:35

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T22:29:19', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'dbd85a34-6ac8-4a82-8ea9-e05ba8ca90a1' User entered 'None (0)'	System	08 Aug 2020 03:29:35
	System	08 Aug 2020 03:29:35

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:54:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T22:29:21', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'dbd85a34-6ac8-4a82-8ea9-e05ba8ca90a1' User entered 'None (0)'	System	08 Aug 2020 03:29:35
	System	08 Aug 2020 03:29:35

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T22:29:23', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'dbd85a34-6ac8-4a82-8ea9-e05ba8ca90a1' User entered 'None (0)'	System	08 Aug 2020 03:29:35
	System	08 Aug 2020 03:29:35

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:54:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T22:29:25', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'dbd85a34-6ac8-4a82-8ea9-e05ba8ca90a1' User entered 'None (0)'	System	08 Aug 2020 03:29:35
	System	08 Aug 2020 03:29:35

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:54:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T22:29:27', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'dbd85a34-6ac8-4a82-8ea9-e05ba8ca90a1' User entered 'None (0)'	System	08 Aug 2020 03:29:35
	System	08 Aug 2020 03:29:35



US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T22:29:29', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'dbd85a34-6ac8-4a82-8ea9-e05ba8ca90a1' User entered 'No (N)'	System	08 Aug 2020 03:29:35
	System	08 Aug 2020 03:29:35

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-07T22:29:32', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'dbd85a34-6ac8-4a82-8ea9-e05ba8ca90a1' User entered '07 Aug 2020 22:29'	System	08 Aug 2020 03:29:35
	System	08 Aug 2020 03:29:35

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '07 Aug 2020 20:57'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '08 Aug 2020 11:59'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 2'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:54:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-08T21:24:17', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b6e6bf79-5241-43bb-bf26-4dfb5d3f5997'	System	09 Aug 2020 02:25:04
User entered 'None (0)'	System	09 Aug 2020 02:25:04

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:54:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-08T21:24:20', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b6e6bf79-5241-43bb-bf26-4dfb5d3f5997'	System	09 Aug 2020 02:25:04
User entered 'None (0)'	System	09 Aug 2020 02:25:04

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:54:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-08T21:24:22', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b6e6bf79-5241-43bb-bf26-4dfb5d3f5997'	System	09 Aug 2020 02:25:04
User entered 'None (0)'	System	09 Aug 2020 02:25:04



US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:54:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-08T21:24:28', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b6e6bf79-5241-43bb-bf26-4dfb5d3f5997'	System	09 Aug 2020 02:25:04
User entered 'None (0)'	System	09 Aug 2020 02:25:04

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:54:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-08T21:24:36', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b6e6bf79-5241-43bb-bf26-4dfb5d3f5997'	System	09 Aug 2020 02:25:04
User entered 'None (0)'	System	09 Aug 2020 02:25:04

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:54:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-08T21:24:38', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b6e6bf79-5241-43bb-bf26-4dfb5d3f5997'	System	09 Aug 2020 02:25:04
User entered 'None (0)'	System	09 Aug 2020 02:25:04

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:54:48

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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-08T21:24:46', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b6e6bf79-5241-43bb-bf26-4dfb5d3f5997'	System	09 Aug 2020 02:25:04
User entered 'No (N)'	System	09 Aug 2020 02:25:04

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-08T21:24:49', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b6e6bf79-5241-43bb-bf26-4dfb5d3f5997'	System	09 Aug 2020 02:25:04
User entered '08 Aug 2020 21:24'	System	09 Aug 2020 02:25:04

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '08 Aug 2020 12:00'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '09 Aug 2020 11:59'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 3'	System	07 Aug 2020 22:19:27



**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-09T19:26:29', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c2f5976e-e6f2-4d5b-a09d-93917e59f454'	System	10 Aug 2020 00:26:50
User entered 'None (0)'	System	10 Aug 2020 00:26:50

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-09T19:26:32', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c2f5976e-e6f2-4d5b-a09d-93917e59f454'	System	10 Aug 2020 00:26:50
User entered 'None (0)'	System	10 Aug 2020 00:26:50

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-09T19:26:34', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c2f5976e-e6f2-4d5b-a09d-93917e59f454'	System	10 Aug 2020 00:26:50
User entered 'None (0)'	System	10 Aug 2020 00:26:50

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-09T19:26:36', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c2f5976e-e6f2-4d5b-a09d-93917e59f454'	System	10 Aug 2020 00:26:50
User entered 'None (0)'	System	10 Aug 2020 00:26:50

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-09T19:26:40', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c2f5976e-e6f2-4d5b-a09d-93917e59f454'	System	10 Aug 2020 00:26:50
User entered 'None (0)'	System	10 Aug 2020 00:26:50

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-09T19:26:42', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c2f5976e-e6f2-4d5b-a09d-93917e59f454'	System	10 Aug 2020 00:26:50
User entered 'None (0)'	System	10 Aug 2020 00:26:50

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:54:48

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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-09T19:26:46', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c2f5976e-e6f2-4d5b-a09d-93917e59f454'	System	10 Aug 2020 00:26:50
User entered 'No (N)'	System	10 Aug 2020 00:26:50

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-09T19:26:49', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c2f5976e-e6f2-4d5b-a09d-93917e59f454'	System	10 Aug 2020 00:26:50
User entered '09 Aug 2020 19:26'	System	10 Aug 2020 00:26:50



US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '09 Aug 2020 12:00'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '10 Aug 2020 11:59'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 4'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:54:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-10T19:26:31', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'e11ec773-0053-465a-a986-3476dd25c995' User entered 'None (0)'	System	11 Aug 2020 00:26:50
	System	11 Aug 2020 00:26:50

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:54:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-10T19:26:33', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'e11ec773-0053-465a-a986-3476dd25c995' User entered 'None (0)'	System	11 Aug 2020 00:26:50
	System	11 Aug 2020 00:26:50

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:54:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-10T19:26:36', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'e11ec773-0053-465a-a986-3476dd25c995' User entered 'None (0)'	System	11 Aug 2020 00:26:50
	System	11 Aug 2020 00:26:50

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:54:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-10T19:26:38', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'e11ec773-0053-465a-a986-3476dd25c995' User entered 'None (0)'	System	11 Aug 2020 00:26:50
	System	11 Aug 2020 00:26:50

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:54:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-10T19:26:40', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'e11ec773-0053-465a-a986-3476dd25c995' User entered 'None (0)'	System	11 Aug 2020 00:26:50
	System	11 Aug 2020 00:26:50



**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:54:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-10T19:26:42', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'e11ec773-0053-465a-a986-3476dd25c995' User entered 'None (0)'	System	11 Aug 2020 00:26:50
	System	11 Aug 2020 00:26:50

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:54:48

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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-10T19:26:45', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'e11ec773-0053-465a-a986-3476dd25c995'	System	11 Aug 2020 00:26:50
User entered 'No (N)'	System	11 Aug 2020 00:26:50

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-10T19:26:47', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'e11ec773-0053-465a-a986-3476dd25c995'	System	11 Aug 2020 00:26:50
User entered '10 Aug 2020 19:26'	System	11 Aug 2020 00:26:50

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '10 Aug 2020 12:00'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '11 Aug 2020 11:59'	System	07 Aug 2020 22:19:27

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 5'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T05:54:31', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'd19d338f-e9ac-415f-ab07-4150d1d85907' User entered 'None (0)'	System	12 Aug 2020 10:54:55
	System	12 Aug 2020 10:54:55

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T05:54:34', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'd19d338f-e9ac-415f-ab07-4150d1d85907' User entered 'None (0)'	System	12 Aug 2020 10:54:55
	System	12 Aug 2020 10:54:55



**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T05:54:38', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'd19d338f-e9ac-415f-ab07-4150d1d85907' User entered 'None (0)'	System	12 Aug 2020 10:54:55
	System	12 Aug 2020 10:54:55

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:54:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T05:54:41', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'd19d338f-e9ac-415f-ab07-4150d1d85907' User entered 'None (0)'	System	12 Aug 2020 10:54:55
	System	12 Aug 2020 10:54:55

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T05:54:43', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'd19d338f-e9ac-415f-ab07-4150d1d85907' User entered 'None (0)'	System	12 Aug 2020 10:54:55
	System	12 Aug 2020 10:54:55

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T05:54:46', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'd19d338f-e9ac-415f-ab07-4150d1d85907' User entered 'None (0)'	System	12 Aug 2020 10:54:55
	System	12 Aug 2020 10:54:55

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:54:48

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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T05:54:49', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'd19d338f-e9ac-415f-ab07-4150d1d85907'	System	12 Aug 2020 10:54:55
User entered 'No (N)'	System	12 Aug 2020 10:54:55

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T05:54:51', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'd19d338f-e9ac-415f-ab07-4150d1d85907'	System	12 Aug 2020 10:54:55
User entered '12 Aug 2020 05:54'	System	12 Aug 2020 10:54:55

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '11 Aug 2020 12:00'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '12 Aug 2020 11:59'	System	07 Aug 2020 22:19:27



**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 6'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T19:09:39', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'cbb4ba16-4d29-4ce2-b683-fe17bcfc1274' User entered 'None (0)'	System	13 Aug 2020 00:09:52
	System	13 Aug 2020 00:09:52

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:54:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T19:09:41', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'cbb4ba16-4d29-4ce2-b683-fe17bcfc1274' User entered 'None (0)'	System	13 Aug 2020 00:09:52
	System	13 Aug 2020 00:09:52

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T19:09:42', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'cbb4ba16-4d29-4ce2-b683-fe17bcfc1274' User entered 'None (0)'	System	13 Aug 2020 00:09:52
	System	13 Aug 2020 00:09:52

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T19:09:43', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'cbb4ba16-4d29-4ce2-b683-fe17bcfc1274' User entered 'None (0)'	System	13 Aug 2020 00:09:52
	System	13 Aug 2020 00:09:52

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T19:09:45', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'cbb4ba16-4d29-4ce2-b683-fe17bcfc1274' User entered 'None (0)'	System	13 Aug 2020 00:09:52
	System	13 Aug 2020 00:09:52

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T19:09:47', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'cbb4ba16-4d29-4ce2-b683-fe17bcfc1274' User entered 'None (0)'	System	13 Aug 2020 00:09:52
	System	13 Aug 2020 00:09:52

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:54:48

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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T19:09:49', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'cbb4ba16-4d29-4ce2-b683-fe17bcfc1274' User entered 'No (N)'	System	13 Aug 2020 00:09:52
	System	13 Aug 2020 00:09:52



**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-12T19:09:51', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'cbb4ba16-4d29-4ce2-b683-fe17bcfc1274' User entered '12 Aug 2020 19:09'	System	13 Aug 2020 00:09:52
	System	13 Aug 2020 00:09:52

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '12 Aug 2020 12:00'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '13 Aug 2020 11:59'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 7'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-13T21:18:26', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f95bf2b7-2a21-42d5-b7cf-cb6ad6103d5e' User entered 'None (0)'	System	14 Aug 2020 02:18:57
	System	14 Aug 2020 02:18:57

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-13T21:18:28', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f95bf2b7-2a21-42d5-b7cf-cb6ad6103d5e' User entered 'None (0)'	System	14 Aug 2020 02:18:57
	System	14 Aug 2020 02:18:57

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-13T21:18:31', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f95bf2b7-2a21-42d5-b7cf-cb6ad6103d5e' User entered 'None (0)'	System	14 Aug 2020 02:18:57
	System	14 Aug 2020 02:18:57

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:54:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-13T21:18:34', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f95bf2b7-2a21-42d5-b7cf-cb6ad6103d5e' User entered 'None (0)'	System	14 Aug 2020 02:18:57
	System	14 Aug 2020 02:18:57



**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-13T21:18:36', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f95bf2b7-2a21-42d5-b7cf-cb6ad6103d5e' User entered 'None (0)'	System	14 Aug 2020 02:18:57
	System	14 Aug 2020 02:18:57

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-13T21:18:38', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f95bf2b7-2a21-42d5-b7cf-cb6ad6103d5e' User entered 'None (0)'	System	14 Aug 2020 02:18:57
	System	14 Aug 2020 02:18:57

US3812081

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:54:48

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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-13T21:18:53', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f95bf2b7-2a21-42d5-b7cf-cb6ad6103d5e' User entered 'No (N)'	System	14 Aug 2020 02:18:57
	System	14 Aug 2020 02:18:57

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-08-13T21:18:56', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f95bf2b7-2a21-42d5-b7cf-cb6ad6103d5e' User entered '13 Aug 2020 21:18'	System	14 Aug 2020 02:18:57
	System	14 Aug 2020 02:18:57

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '13 Aug 2020 12:00'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '14 Aug 2020 11:59'	System	07 Aug 2020 22:19:27

**US3812081**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	18 Aug 2020 17:11:22

**US3812081**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '15 Aug 2020'	Breanna Galibert (b) (4)	18 Aug 2020 17:11:22



**US3812081**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4)	18 Aug 2020 17:11:22

**US3812081**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Breanna Galibert (b) (4)	18 Aug 2020 17:11:22

US3812081

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	24 Aug 2020 17:52:27

**US3812081**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:54:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User entered 'I'	System	24 Aug 2020 17:52:27

**US3812081**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	24 Aug 2020 17:52:37

**US3812081**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '21 Aug 2020'	Breanna Galibert (b) (4)	24 Aug 2020 17:52:37

**US3812081**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4)	24 Aug 2020 17:52:37

**US3812081**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Breanna Galibert (b) (4)	24 Aug 2020 17:52:37



US3812081

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Angie Kean (b) (4)	29 Aug 2020 18:10:02

**US3812081**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:54:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 08:48:44
User entered 'I'	System	29 Aug 2020 18:10:02

**US3812081**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Angie Kean (b) (4)	29 Aug 2020 18:10:14

**US3812081**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '28 Aug 2020'	Angie Kean (b) (4)	29 Aug 2020 18:10:14

**US3812081**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Contact Made (CONTACT MADE)'	Angie Kean (b) (4)	29 Aug 2020 18:10:14

US3812081

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Angie Kean (b) (4)	29 Aug 2020 18:10:14

US3812081

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:16
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Heather Cherniawski	02 Sep 2020 22:45:14

**US3812081**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:54:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 10:20:16
User entered 'I'	System	02 Sep 2020 22:45:14



US3812081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:48

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 02SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	28 Dec 2020 09:11:04
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 02SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking details in the response. Thank you.' answered with 'DCF FAXED 02 SEP 2020. SEE ACCESSION NUMBER 1F600646178' (Site from DM).	Anya Penly (b) (4)	23 Dec 2020 18:01:20
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Sample dated 02SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number and tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Dec 2020 06:50:57
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	02 Sep 2020 22:45:27

US3812081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:48

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User closed query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	11 Sep 2020 09:25:03
Query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'Subject within window' (Site from System).	Anya Penly (b) (4)	04 Sep 2020 22:44:59
	(b) (4)	
User opened query 'Visit 2 Date is < 28 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	02 Sep 2020 22:45:27
User entered '2 Sep 2020'	Heather Cherniawski	02 Sep 2020 22:45:27
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Clinic (Clinic)'	Heather Cherniawski	02 Sep 2020 22:45:27
	(b) (4)	

**US3812081**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:54:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'VISIT2'	System	02 Sep 2020 22:45:27

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '2 Sep 2020'	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '16:30'	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	



US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered '2 Sep 2020 16:30'	System	11 Sep 2020 18:04:29

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '98.1' F	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '47'	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	

**US3812081**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'bpm'	System	11 Sep 2020 18:04:29

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '16'	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'breaths/min'	System	11 Sep 2020 18:04:29



US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '124'	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'mmHg'	System	11 Sep 2020 18:04:29

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '78'	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:54:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'mmHg'	System	11 Sep 2020 18:04:29

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '2 Sep 2020'	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '17:51'	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	



US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered '2 Sep 2020 17:51'	System	11 Sep 2020 18:04:29

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '97.1' F	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '47'	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	

**US3812081**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'bpm'	System	11 Sep 2020 18:04:29

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '16'	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'breaths/min'	System	11 Sep 2020 18:04:29



US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '122'	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'mmHg'	System	11 Sep 2020 18:04:29

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '75'	Breanna Galibert (b) (4)	11 Sep 2020 18:04:29
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:54:48

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'mmHg'	System	11 Sep 2020 18:04:29

US3812081

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:48

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Sep 2020 18:02:58
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	11 Sep 2020 18:02:58
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:48

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Yes (Y)'	Heather Cherniawski	02 Sep 2020 22:45:55
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:48

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered empty.	Heather Cherniawski	02 Sep 2020 22:45:55
	(b) (4)	



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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:48

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 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered empty.	Heather Cherniawski	02 Sep 2020 22:45:55
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:48

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 22:45:55

US3812081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:48

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '2 Sep 2020'	Heather Cherniawski	02 Sep 2020 22:45:55
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:48

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '17:20'	Heather Cherniawski	02 Sep 2020 22:45:55
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:48

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered '2 Sep 2020 17:20'	System	02 Sep 2020 22:45:55

US3812081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:48

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Heather Cherniawski	02 Sep 2020 22:45:55
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:48

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'ONCE'	System	02 Sep 2020 22:45:55

US3812081

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:54:48

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 22:45:55



US3812081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Sep 2020 18:03:19
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
	(b) (4)	
	(b) (4), (b) (6)	
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 2Sep2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 16:51:19
	(b) (4)	
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 2Sep2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' answered with 'DATA IS CORRECT. UNSCHEDULED KIT WAS USED PER SPONSOR DUE TO NO SUPPLIES ON SITE. PPD WAS NOTIFIED TO UPDATE.' (Site from DM).	Angie Kean (b) (4)	26 Oct 2020 14:38:17
	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 2Sep2020 is recorded under Visit 2 Day 29 visit in EDC, however the same is reported under Unscheduled visit in PPD Central lab. Please reconcile the correct Visit and update if applicable. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:59:11
	(b) (4)	
User entered '2 Sep 2020'	Breanna Galibert (b) (4)	11 Sep 2020 18:03:19
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:48

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '17:03'	Breanna Galibert (b) (4)	11 Sep 2020 18:03:19
	(b) (4)	

**US3812081**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:54:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered '2 Sep 2020 17:03'	System	11 Sep 2020 18:03:19

US3812081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:54:48

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
	(b) (4)	
	(b) (4)	
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User closed query 'Per GCL Lab Recon: Nasopharyngeal Swab: Sample dated 02Sep2020 under Visit2 Day29 visit in EDC, however the Sample dated 02Sep2020 is recorded under Unscheduled visit in PPD Central lab. Please review and confirm the correct date.' (Site from DM). Query 'Per GCL Lab Recon: Nasopharyngeal Swab: Sample dated 02Sep2020 under Visit2 Day29 visit in EDC, however the Sample dated 02Sep2020 is recorded under Unscheduled visit in PPD Central lab. Please review and confirm the correct date.' answered with 'DATA IS CORRECT. UNSCHEDULED KIT WAS USED PER SPONSOR. GCL WAS NOTIFIED TO UPDATE' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 06:58:34
	(b) (4)	
Query 'Per GCL Lab Recon: Nasopharyngeal Swab: Sample dated 02Sep2020 under Visit2 Day29 visit in EDC, however the Sample dated 02Sep2020 is recorded under Unscheduled visit in PPD Central lab. Please review and confirm the correct date.' answered with 'DATA IS CORRECT. UNSCHEDULED KIT WAS USED PER SPONSOR. GCL WAS NOTIFIED TO UPDATE' (Site from DM).	Angie Kean (b) (4)	23 Nov 2020 16:59:55
	(b) (4)	
User opened query 'Per GCL Lab Recon: Nasopharyngeal Swab: Sample dated 02Sep2020 under Visit2 Day29 visit in EDC, however the Sample dated 02Sep2020 is recorded under Unscheduled visit in PPD Central lab. Please review and confirm the correct date.' (Site from DM).	(b) (4), (b) (6)	22 Nov 2020 23:13:33
	(b) (4)	
User entered '2 Sep 2020'	Breanna Galibert (b) (4)	11 Sep 2020 18:03:33
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:54:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Breanna Galibert (b) (4)	11 Sep 2020 18:03:33
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:54:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	11 Sep 2020 18:03:33
	(b) (4)	

**US3812081**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:54:48**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '17:06'	Breanna Galibert (b) (4)	11 Sep 2020 18:03:33
	(b) (4)	



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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:54:48

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
Query 'Per GCL Lab Recon: Nasopharyngeal Swab: Sample dated 02SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however the sample is missing in PPD Central lab. Please provide Accession number and Tracking details in the response. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	26 Apr 2021 12:49:35
User opened query 'Per GCL Lab Recon: Nasopharyngeal Swab: Sample dated 02SEP2020 is recorded under Visit 2 Day 29 visit in EDC, however the sample is missing in PPD Central lab. Please provide Accession number and Tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	15 Jan 2021 05:02:41
User entered '2 Sep 2020 17:06'	System	11 Sep 2020 18:03:33

US3812081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:54:48

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Breanna Galibert (b) (4)	11 Sep 2020 18:03:33
	(b) (4)	

US3812081

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:54:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	11 Sep 2020 18:03:33
	(b) (4)	

**US3812081**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	11 Sep 2020 18:03:33
	(b) (4)	

**US3812081**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered empty.	System	11 Sep 2020 18:03:33

US3812081

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Yes (Y)'	Karen Knapp (b) (4)	09 Sep 2020 19:59:11
	(b) (4)	

**US3812081**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:54:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'I'	System	09 Sep 2020 19:59:11

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:45:55



US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-02T17:54:05', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f1c4efa4-5082-49b5-81f6-566d6ed528f1' User entered 'Yes (Y)'	System	02 Sep 2020 22:54:23
	System	02 Sep 2020 22:54:23

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-02T17:54:11', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f1c4efa4-5082-49b5-81f6-566d6ed528f1' User entered '97.1'	System	02 Sep 2020 22:54:23
	System	02 Sep 2020 22:54:23

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-02T17:54:15', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f1c4efa4-5082-49b5-81f6-566d6ed528f1' User entered 'No (N)'	System	02 Sep 2020 22:54:23
	System	02 Sep 2020 22:54:23

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-02T17:54:20', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f1c4efa4-5082-49b5-81f6-566d6ed528f1' User entered '02 Sep 2020 17:54'	System	02 Sep 2020 22:54:23
	System	02 Sep 2020 22:54:23

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '02 Sep 2020 17:40'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '02 Sep 2020 20:10'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T06:09:58', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'd7b3e2f8-0f18-488e-9dc2-418d7e94c954'	System	03 Sep 2020 11:10:17
User entered 'Yes (Y)'	System	03 Sep 2020 11:10:17



US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T06:10:04', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'd7b3e2f8-0f18-488e-9dc2-418d7e94c954' User entered '97.1'	System	03 Sep 2020 11:10:17
	System	03 Sep 2020 11:10:17

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T06:10:11', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'd7b3e2f8-0f18-488e-9dc2-418d7e94c954'	System	03 Sep 2020 11:10:17
User entered 'No (N)'	System	03 Sep 2020 11:10:17

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T06:10:15', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'd7b3e2f8-0f18-488e-9dc2-418d7e94c954'	System	03 Sep 2020 11:10:17
User entered '03 Sep 2020 06:10'	System	03 Sep 2020 11:10:17

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '02 Sep 2020 21:05'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 2'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T19:26:50', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '7f730986-1cf7-4047-9d44-4e07212874b3' User entered 'Yes (Y)'	System	04 Sep 2020 00:27:09
	System	04 Sep 2020 00:27:09

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T19:26:55', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '7f730986-1cf7-4047-9d44-4e07212874b3' User entered '99.6'	System	04 Sep 2020 00:27:09
	System	04 Sep 2020 00:27:09



US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T19:27:01', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '7f730986-1cf7-4047-9d44-4e07212874b3'	System	04 Sep 2020 00:27:09
User entered 'No (N)'	System	04 Sep 2020 00:27:09

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T19:27:06', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '7f730986-1cf7-4047-9d44-4e07212874b3'	System	04 Sep 2020 00:27:09
User entered '03 Sep 2020 19:27'	System	04 Sep 2020 00:27:09

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 3'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-05T09:36:02', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '1d51932e-f6e3-4b74-aa39-de25f5870c52' User entered 'Yes (Y)'	System	05 Sep 2020 13:36:21
	System	05 Sep 2020 13:36:21

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-05T09:36:08', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '1d51932e-f6e3-4b74-aa39-de25f5870c52' User entered '96.6'	System	05 Sep 2020 13:36:21
	System	05 Sep 2020 13:36:21

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-05T09:36:17', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '1d51932e-f6e3-4b74-aa39-de25f5870c52'	System	05 Sep 2020 13:36:21
User entered 'No (N)'	System	05 Sep 2020 13:36:21



**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-05T09:36:20', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '1d51932e-f6e3-4b74-aa39-de25f5870c52' User entered '05 Sep 2020 09:36'	System	05 Sep 2020 13:36:21
	System	05 Sep 2020 13:36:21

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 4'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T08:51:26', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '54c22998-19f8-4d50-ae8c-08f85f35f568'	System	06 Sep 2020 12:51:50
User entered 'Yes (Y)'	System	06 Sep 2020 12:51:50

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T08:51:33', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '54c22998-19f8-4d50-ae8c-08f85f35f568'	System	06 Sep 2020 12:51:50
User entered '96.0'	System	06 Sep 2020 12:51:50

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T08:51:37', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '54c22998-19f8-4d50-ae8c-08f85f35f568'	System	06 Sep 2020 12:51:50
User entered 'No (N)'	System	06 Sep 2020 12:51:50

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T08:51:49', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '54c22998-19f8-4d50-ae8c-08f85f35f568'	System	06 Sep 2020 12:51:50
User entered '06 Sep 2020 08:51'	System	06 Sep 2020 12:51:50



US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 5'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T21:11:42', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'ee71a37a-8d6f-444d-b78b-99beb4eb88da' User entered 'Yes (Y)'	System	07 Sep 2020 01:11:57
	System	07 Sep 2020 01:11:57

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T21:11:48', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'ee71a37a-8d6f-444d-b78b-99beb4eb88da' User entered '97.1'	System	07 Sep 2020 01:11:57
	System	07 Sep 2020 01:11:57

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T21:11:52', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'ee71a37a-8d6f-444d-b78b-99beb4eb88da'	System	07 Sep 2020 01:11:57
User entered 'No (N)'	System	07 Sep 2020 01:11:57

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T21:11:56', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'ee71a37a-8d6f-444d-b78b-99beb4eb88da' User entered '06 Sep 2020 21:11'	System	07 Sep 2020 01:11:57
	System	07 Sep 2020 01:11:57

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:45:55



US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 6'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T06:14:15', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '6fb72a23-7ee9-4e5d-a318-44af903d5d98'	System	08 Sep 2020 11:14:30
User entered 'Yes (Y)'	System	08 Sep 2020 11:14:30

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T06:14:20', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '6fb72a23-7ee9-4e5d-a318-44af903d5d98'	System	08 Sep 2020 11:14:30
User entered '98.4'	System	08 Sep 2020 11:14:30

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T06:14:24', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '6fb72a23-7ee9-4e5d-a318-44af903d5d98'	System	08 Sep 2020 11:14:30
User entered 'No (N)'	System	08 Sep 2020 11:14:30

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T06:14:27', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '6fb72a23-7ee9-4e5d-a318-44af903d5d98'	System	08 Sep 2020 11:14:30
User entered '08 Sep 2020 06:14'	System	08 Sep 2020 11:14:30

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:45:55



US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 7'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:54:48

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T22:17:22', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'd0c4ad22-bd2c-4aa8-9c96-be9781afff7c' User entered 'Yes (Y)'	System	09 Sep 2020 03:17:49
	System	09 Sep 2020 03:17:49

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:54:48

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T22:17:36', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'd0c4ad22-bd2c-4aa8-9c96-be9781afff7c' User entered '97.2'	System	09 Sep 2020 03:17:49
	System	09 Sep 2020 03:17:49

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T22:17:44', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'd0c4ad22-bd2c-4aa8-9c96-be9781afff7c' User entered 'No (N)'	System	09 Sep 2020 03:17:49
	System	09 Sep 2020 03:17:49

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T22:17:47', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'd0c4ad22-bd2c-4aa8-9c96-be9781afff7c' User entered '08 Sep 2020 22:17'	System	09 Sep 2020 03:17:49
	System	09 Sep 2020 03:17:49

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:45:55



US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-02T17:54:25', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '3afc39c6-2cba-4ea2-b707-21c9146fd3af'	System	02 Sep 2020 22:54:42
User entered 'None (1)'	System	02 Sep 2020 22:54:42

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-02T17:54:28', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '3afc39c6-2cba-4ea2-b707-21c9146fd3af' User entered 'No (N)'	System	02 Sep 2020 22:54:42
	System	02 Sep 2020 22:54:42

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-02T17:54:32', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '3afc39c6-2cba-4ea2-b707-21c9146fd3af' User entered 'No (N)'	System	02 Sep 2020 22:54:42
	System	02 Sep 2020 22:54:42

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-02T17:54:35', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '3afc39c6-2cba-4ea2-b707-21c9146fd3af'	System	02 Sep 2020 22:54:42
User entered 'None (1)'	System	02 Sep 2020 22:54:42

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-02T17:54:38', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '3afc39c6-2cba-4ea2-b707-21c9146fd3af' User entered '02 Sep 2020 17:54'	System	02 Sep 2020 22:54:42
	System	02 Sep 2020 22:54:42

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '02 Sep 2020 17:40'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '02 Sep 2020 20:10'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:45:55



US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T06:10:26', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '8e09e4a7-8d79-435c-8209-1d58cb715938'	System	03 Sep 2020 11:10:43
User entered 'None (1)'	System	03 Sep 2020 11:10:43

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T06:10:31', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '8e09e4a7-8d79-435c-8209-1d58cb715938'	System	03 Sep 2020 11:10:43
User entered 'No (N)'	System	03 Sep 2020 11:10:43

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T06:10:33', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '8e09e4a7-8d79-435c-8209-1d58cb715938'	System	03 Sep 2020 11:10:43
User entered 'No (N)'	System	03 Sep 2020 11:10:43

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T06:10:37', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '8e09e4a7-8d79-435c-8209-1d58cb715938'	System	03 Sep 2020 11:10:43
User entered 'None (1)'	System	03 Sep 2020 11:10:43

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T06:10:41', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '8e09e4a7-8d79-435c-8209-1d58cb715938'	System	03 Sep 2020 11:10:43
User entered '03 Sep 2020 06:10'	System	03 Sep 2020 11:10:43

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '02 Sep 2020 21:05'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 2'	System	02 Sep 2020 22:45:55



US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T19:27:21', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b1be5280-3158-4443-b701-981ee4abd07e'	System	04 Sep 2020 00:29:24
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 00:29:24

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:54:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T19:27:48', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b1be5280-3158-4443-b701-981ee4abd07e' User entered 'No (N)'	System	04 Sep 2020 00:29:24
	System	04 Sep 2020 00:29:24

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T19:28:04', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b1be5280-3158-4443-b701-981ee4abd07e' User entered 'Yes (Y)'	System	04 Sep 2020 00:29:24
	System	04 Sep 2020 00:29:24

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:54:48

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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T19:29:12', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b1be5280-3158-4443-b701-981ee4abd07e'	System	04 Sep 2020 00:29:24
User entered '80'	System	04 Sep 2020 00:29:24

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T19:29:19', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b1be5280-3158-4443-b701-981ee4abd07e' User entered 'None (1)'	System	04 Sep 2020 00:29:24
	System	04 Sep 2020 00:29:24

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T19:29:21', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b1be5280-3158-4443-b701-981ee4abd07e' User entered '03 Sep 2020 19:29'	System	04 Sep 2020 00:29:24
	System	04 Sep 2020 00:29:24

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:45:55



US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 3'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-05T09:34:16', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'e9fea78f-ce87-4a5c-9c0f-fdd55405a432'	System	05 Sep 2020 13:35:05
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 13:35:05

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:54:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-05T09:34:23', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'e9fea78f-ce87-4a5c-9c0f-fdd55405a432'	System	05 Sep 2020 13:35:05
User entered 'No (N)'	System	05 Sep 2020 13:35:05

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-05T09:34:34', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'e9fea78f-ce87-4a5c-9c0f-fdd55405a432'	System	05 Sep 2020 13:35:05
User entered 'Yes (Y)'	System	05 Sep 2020 13:35:05

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:54:48

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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-05T09:34:44', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'e9fea78f-ce87-4a5c-9c0f-fdd55405a432'	System	05 Sep 2020 13:35:05
User entered '90'	System	05 Sep 2020 13:35:05

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-05T09:34:58', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'e9fea78f-ce87-4a5c-9c0f-fdd55405a432'	System	05 Sep 2020 13:35:05
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 13:35:05

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-05T09:35:02', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'e9fea78f-ce87-4a5c-9c0f-fdd55405a432'	System	05 Sep 2020 13:35:05
User entered '05 Sep 2020 09:35'	System	05 Sep 2020 13:35:05

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:45:55



US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 4'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T08:49:27', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '181b77a6-43ae-4e7e-8443-139bc56a3742'	System	06 Sep 2020 12:49:52
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 12:49:52

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:54:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T08:49:31', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '181b77a6-43ae-4e7e-8443-139bc56a3742'	System	06 Sep 2020 12:49:52
User entered 'No (N)'	System	06 Sep 2020 12:49:52

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T08:49:34', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '181b77a6-43ae-4e7e-8443-139bc56a3742'	System	06 Sep 2020 12:49:52
User entered 'Yes (Y)'	System	06 Sep 2020 12:49:52

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:54:48

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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T08:49:41', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '181b77a6-43ae-4e7e-8443-139bc56a3742' User entered '32'	System	06 Sep 2020 12:49:52
	System	06 Sep 2020 12:49:52

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T08:49:44', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '181b77a6-43ae-4e7e-8443-139bc56a3742'	System	06 Sep 2020 12:49:52
User entered 'None (1)'	System	06 Sep 2020 12:49:52

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T08:49:48', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '181b77a6-43ae-4e7e-8443-139bc56a3742' User entered '06 Sep 2020 08:49'	System	06 Sep 2020 12:49:52
	System	06 Sep 2020 12:49:52



US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 5'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T21:12:02', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'e61b8c6b-40cd-42ea-82d9-ec8254e70f71' User entered 'None (1)'	System	07 Sep 2020 01:12:21
	System	07 Sep 2020 01:12:21

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:54:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T21:12:08', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'e61b8c6b-40cd-42ea-82d9-ec8254e70f71' User entered 'No (N)'	System	07 Sep 2020 01:12:21
	System	07 Sep 2020 01:12:21

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T21:12:11', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'e61b8c6b-40cd-42ea-82d9-ec8254e70f71' User entered 'No (N)'	System	07 Sep 2020 01:12:21
	System	07 Sep 2020 01:12:21

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T21:12:15', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'e61b8c6b-40cd-42ea-82d9-ec8254e70f71' User entered 'None (1)'	System	07 Sep 2020 01:12:21
	System	07 Sep 2020 01:12:21

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T21:12:17', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'e61b8c6b-40cd-42ea-82d9-ec8254e70f71' User entered '06 Sep 2020 21:12'	System	07 Sep 2020 01:12:21
	System	07 Sep 2020 01:12:21



**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 6'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T06:14:31', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'd803b8f6-5bbb-4475-86bf-c27fb067e1b0'	System	08 Sep 2020 11:14:53
User entered 'None (1)'	System	08 Sep 2020 11:14:53

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:54:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T06:14:35', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'd803b8f6-5bbb-4475-86bf-c27fb067e1b0'	System	08 Sep 2020 11:14:53
User entered 'No (N)'	System	08 Sep 2020 11:14:53

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T06:14:38', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'd803b8f6-5bbb-4475-86bf-c27fb067e1b0' User entered 'No (N)'	System	08 Sep 2020 11:14:53
	System	08 Sep 2020 11:14:53

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T06:14:40', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'd803b8f6-5bbb-4475-86bf-c27fb067e1b0'	System	08 Sep 2020 11:14:53
User entered 'None (1)'	System	08 Sep 2020 11:14:53

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T06:14:50', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'd803b8f6-5bbb-4475-86bf-c27fb067e1b0' User entered '08 Sep 2020 06:14'	System	08 Sep 2020 11:14:53
	System	08 Sep 2020 11:14:53



US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:54:48

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 7'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T22:17:01', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b8bf7b57-a5c6-4443-8531-5cd0febb2910'	System	09 Sep 2020 03:17:15
User entered 'None (1)'	System	09 Sep 2020 03:17:15

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:54:48

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T22:17:04', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b8bf7b57-a5c6-4443-8531-5cd0febb2910'	System	09 Sep 2020 03:17:15
User entered 'No (N)'	System	09 Sep 2020 03:17:15

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:54:48

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T22:17:07', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b8bf7b57-a5c6-4443-8531-5cd0febb2910' User entered 'No (N)'	System	09 Sep 2020 03:17:15
	System	09 Sep 2020 03:17:15

US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:54:48

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T22:17:09', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b8bf7b57-a5c6-4443-8531-5cd0febb2910' User entered 'None (1)'	System	09 Sep 2020 03:17:15
	System	09 Sep 2020 03:17:15

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T22:17:13', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b8bf7b57-a5c6-4443-8531-5cd0febb2910' User entered '08 Sep 2020 22:17'	System	09 Sep 2020 03:17:15
	System	09 Sep 2020 03:17:15



US3812081

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:54:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-02T17:54:45', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'bf811cb8-cf97-4fc8-a56b-ed1281517c46' User entered 'None (0)'	System	02 Sep 2020 22:55:07
	System	02 Sep 2020 22:55:07

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-02T17:54:48', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'bf811cb8-cf97-4fc8-a56b-ed1281517c46' User entered 'None (0)'	System	02 Sep 2020 22:55:07
	System	02 Sep 2020 22:55:07

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-02T17:54:50', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'bf811cb8-cf97-4fc8-a56b-ed1281517c46' User entered 'None (0)'	System	02 Sep 2020 22:55:07
	System	02 Sep 2020 22:55:07

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-02T17:54:52', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'bf811cb8-cf97-4fc8-a56b-ed1281517c46' User entered 'None (0)'	System	02 Sep 2020 22:55:07
	System	02 Sep 2020 22:55:07

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:54:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-02T17:54:54', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'bf811cb8-cf97-4fc8-a56b-ed1281517c46' User entered 'None (0)'	System	02 Sep 2020 22:55:07
	System	02 Sep 2020 22:55:07



**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:54:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-02T17:54:56', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'bf811cb8-cf97-4fc8-a56b-ed1281517c46' User entered 'None (0)'	System	02 Sep 2020 22:55:07
	System	02 Sep 2020 22:55:07

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-02T17:55:02', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'bf811cb8-cf97-4fc8-a56b-ed1281517c46'	System	02 Sep 2020 22:55:07
User entered 'No (N)'	System	02 Sep 2020 22:55:07

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-02T17:55:04', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'bf811cb8-cf97-4fc8-a56b-ed1281517c46'	System	02 Sep 2020 22:55:07
User entered '02 Sep 2020 17:55'	System	02 Sep 2020 22:55:07

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '02 Sep 2020 17:40'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '02 Sep 2020 20:10'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:54:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T06:10:46', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'dc9d9864-1f05-41f0-90a4-38f659ea1a87'	System	03 Sep 2020 11:11:07
User entered 'None (0)'	System	03 Sep 2020 11:11:07

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:54:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T06:10:48', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'dc9d9864-1f05-41f0-90a4-38f659ea1a87' User entered 'None (0)'	System	03 Sep 2020 11:11:07
	System	03 Sep 2020 11:11:07



US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T06:10:50', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'dc9d9864-1f05-41f0-90a4-38f659ea1a87'	System	03 Sep 2020 11:11:07
User entered 'None (0)'	System	03 Sep 2020 11:11:07

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T06:10:53', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'dc9d9864-1f05-41f0-90a4-38f659ea1a87' User entered 'None (0)'	System	03 Sep 2020 11:11:07
	System	03 Sep 2020 11:11:07

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:54:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T06:10:55', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'dc9d9864-1f05-41f0-90a4-38f659ea1a87' User entered 'None (0)'	System	03 Sep 2020 11:11:07
	System	03 Sep 2020 11:11:07

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:54:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T06:10:58', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'dc9d9864-1f05-41f0-90a4-38f659ea1a87'	System	03 Sep 2020 11:11:07
User entered 'None (0)'	System	03 Sep 2020 11:11:07

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T06:11:02', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'dc9d9864-1f05-41f0-90a4-38f659ea1a87'	System	03 Sep 2020 11:11:07
User entered 'No (N)'	System	03 Sep 2020 11:11:07

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T06:11:04', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'dc9d9864-1f05-41f0-90a4-38f659ea1a87' User entered '03 Sep 2020 06:11'	System	03 Sep 2020 11:11:07
	System	03 Sep 2020 11:11:07

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:54:48

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '02 Sep 2020 21:05'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 22:45:55



US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 2'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:54:48

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T19:29:42', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'fd9c875d-ce5a-41bb-9fc2-08ffbb45a9c0'	System	04 Sep 2020 00:30:41
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	04 Sep 2020 00:30:41

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:54:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T19:29:49', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'fd9c875d-ce5a-41bb-9fc2-08ffbb45a9c0'	System	04 Sep 2020 00:30:41
User entered 'Some interference with activity (2)'	System	04 Sep 2020 00:30:41

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:54:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T19:29:57', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'fd9c875d-ce5a-41bb-9fc2-08ffbb45a9c0'	System	04 Sep 2020 00:30:41
User entered 'Some interference with activity (2)'	System	04 Sep 2020 00:30:41

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:54:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T19:30:01', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'fd9c875d-ce5a-41bb-9fc2-08ffbb45a9c0'	System	04 Sep 2020 00:30:41
User entered 'Some interference with activity (2)'	System	04 Sep 2020 00:30:41

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:54:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T19:30:16', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'fd9c875d-ce5a-41bb-9fc2-08ffbb45a9c0'	System	04 Sep 2020 00:30:41
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	04 Sep 2020 00:30:41

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:54:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T19:30:29', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'fd9c875d-ce5a-41bb-9fc2-08ffbb45a9c0'	System	04 Sep 2020 00:30:41
User entered 'No interference with activity (1)'	System	04 Sep 2020 00:30:41

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:54:48

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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T19:30:34', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'fd9c875d-ce5a-41bb-9fc2-08ffbb45a9c0'	System	04 Sep 2020 00:30:41
User entered 'No (N)'	System	04 Sep 2020 00:30:41



**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-03T19:30:37', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'fd9c875d-ce5a-41bb-9fc2-08ffbb45a9c0'	System	04 Sep 2020 00:30:41
User entered '03 Sep 2020 19:30'	System	04 Sep 2020 00:30:41

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 3'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-05T09:35:08', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '728d5096-21ee-481b-b460-847d94a55632' User entered 'None (0)'	System	05 Sep 2020 13:35:49
	System	05 Sep 2020 13:35:49

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-05T09:35:20', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '728d5096-21ee-481b-b460-847d94a55632'	System	05 Sep 2020 13:35:49
User entered 'None (0)'	System	05 Sep 2020 13:35:49

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-05T09:35:26', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '728d5096-21ee-481b-b460-847d94a55632'	System	05 Sep 2020 13:35:49
User entered 'None (0)'	System	05 Sep 2020 13:35:49

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:54:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-05T09:35:29', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '728d5096-21ee-481b-b460-847d94a55632' User entered 'None (0)'	System	05 Sep 2020 13:35:49
	System	05 Sep 2020 13:35:49



**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-05T09:35:32', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '728d5096-21ee-481b-b460-847d94a55632' User entered 'None (0)'	System	05 Sep 2020 13:35:49
	System	05 Sep 2020 13:35:49

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-05T09:35:35', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '728d5096-21ee-481b-b460-847d94a55632'	System	05 Sep 2020 13:35:49
User entered 'None (0)'	System	05 Sep 2020 13:35:49

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:54:48

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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-05T09:35:39', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '728d5096-21ee-481b-b460-847d94a55632'	System	05 Sep 2020 13:35:49
User entered 'No (N)'	System	05 Sep 2020 13:35:49

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-05T09:35:46', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '728d5096-21ee-481b-b460-847d94a55632'	System	05 Sep 2020 13:35:49
User entered '05 Sep 2020 09:35'	System	05 Sep 2020 13:35:49

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 4'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:54:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T08:49:52', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '0fc12f72-61cf-487e-bdc5-30b3023c2cb0' User entered 'None (0)'	System	06 Sep 2020 12:50:08
	System	06 Sep 2020 12:50:08



**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:54:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T08:49:53', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '0fc12f72-61cf-487e-bdc5-30b3023c2cb0' User entered 'None (0)'	System	06 Sep 2020 12:50:08
	System	06 Sep 2020 12:50:08

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:54:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T08:49:55', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '0fc12f72-61cf-487e-bdc5-30b3023c2cb0' User entered 'None (0)'	System	06 Sep 2020 12:50:08
	System	06 Sep 2020 12:50:08

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:54:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T08:49:57', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '0fc12f72-61cf-487e-bdc5-30b3023c2cb0' User entered 'None (0)'	System	06 Sep 2020 12:50:08
	System	06 Sep 2020 12:50:08

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:54:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T08:49:58', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '0fc12f72-61cf-487e-bdc5-30b3023c2cb0' User entered 'None (0)'	System	06 Sep 2020 12:50:08
	System	06 Sep 2020 12:50:08

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:54:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T08:50:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '0fc12f72-61cf-487e-bdc5-30b3023c2cb0' User entered 'None (0)'	System	06 Sep 2020 12:50:08
	System	06 Sep 2020 12:50:08

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:54:48

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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T08:50:03', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '0fc12f72-61cf-487e-bdc5-30b3023c2cb0' User entered 'No (N)'	System	06 Sep 2020 12:50:08
	System	06 Sep 2020 12:50:08

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T08:50:05', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '0fc12f72-61cf-487e-bdc5-30b3023c2cb0' User entered '06 Sep 2020 08:50'	System	06 Sep 2020 12:50:08
	System	06 Sep 2020 12:50:08

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 22:45:55



**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 5'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T21:12:25', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c23c64c7-f7f8-4492-8a31-02dce864ef72'	System	07 Sep 2020 01:12:44
User entered 'None (0)'	System	07 Sep 2020 01:12:44

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T21:12:27', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c23c64c7-f7f8-4492-8a31-02dce864ef72'	System	07 Sep 2020 01:12:44
User entered 'None (0)'	System	07 Sep 2020 01:12:44

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T21:12:28', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c23c64c7-f7f8-4492-8a31-02dce864ef72'	System	07 Sep 2020 01:12:44
User entered 'None (0)'	System	07 Sep 2020 01:12:44

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:54:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T21:12:29', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c23c64c7-f7f8-4492-8a31-02dce864ef72'	System	07 Sep 2020 01:12:44
User entered 'None (0)'	System	07 Sep 2020 01:12:44

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T21:12:31', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c23c64c7-f7f8-4492-8a31-02dce864ef72'	System	07 Sep 2020 01:12:44
User entered 'None (0)'	System	07 Sep 2020 01:12:44

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T21:12:33', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c23c64c7-f7f8-4492-8a31-02dce864ef72'	System	07 Sep 2020 01:12:44
User entered 'None (0)'	System	07 Sep 2020 01:12:44



US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:54:48

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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T21:12:34', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c23c64c7-f7f8-4492-8a31-02dce864ef72'	System	07 Sep 2020 01:12:44
User entered 'No (N)'	System	07 Sep 2020 01:12:44

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-06T21:12:40', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'c23c64c7-f7f8-4492-8a31-02dce864ef72'	System	07 Sep 2020 01:12:44
User entered '06 Sep 2020 21:12'	System	07 Sep 2020 01:12:44

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 6'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T06:14:53', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '6af45265-320e-456f-9b69-ed5c2e3da254' User entered 'None (0)'	System	08 Sep 2020 11:15:14
	System	08 Sep 2020 11:15:14

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T06:14:56', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '6af45265-320e-456f-9b69-ed5c2e3da254' User entered 'None (0)'	System	08 Sep 2020 11:15:14
	System	08 Sep 2020 11:15:14

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:54:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T06:14:58', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '6af45265-320e-456f-9b69-ed5c2e3da254' User entered 'None (0)'	System	08 Sep 2020 11:15:14
	System	08 Sep 2020 11:15:14



US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:54:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T06:15:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '6af45265-320e-456f-9b69-ed5c2e3da254' User entered 'None (0)'	System	08 Sep 2020 11:15:14
	System	08 Sep 2020 11:15:14

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T06:15:02', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '6af45265-320e-456f-9b69-ed5c2e3da254' User entered 'None (0)'	System	08 Sep 2020 11:15:14
	System	08 Sep 2020 11:15:14

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T06:15:04', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '6af45265-320e-456f-9b69-ed5c2e3da254' User entered 'None (0)'	System	08 Sep 2020 11:15:14
	System	08 Sep 2020 11:15:14

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:54:48

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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T06:15:08', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '6af45265-320e-456f-9b69-ed5c2e3da254'	System	08 Sep 2020 11:15:14
User entered 'No (N)'	System	08 Sep 2020 11:15:14

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T06:15:11', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '6af45265-320e-456f-9b69-ed5c2e3da254'	System	08 Sep 2020 11:15:14
User entered '08 Sep 2020 06:15'	System	08 Sep 2020 11:15:14

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 22:45:55

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:54:48

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	02 Sep 2020 22:45:55
User entered 'Day 7'	System	02 Sep 2020 22:45:55



**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T22:16:26', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '025038cf-6015-471d-92d5-06751ed3662a' User entered 'None (0)'	System	09 Sep 2020 03:16:55
	System	09 Sep 2020 03:16:55

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:54:48

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T22:16:28', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '025038cf-6015-471d-92d5-06751ed3662a' User entered 'None (0)'	System	09 Sep 2020 03:16:55
	System	09 Sep 2020 03:16:55

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:54:48

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T22:16:30', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '025038cf-6015-471d-92d5-06751ed3662a' User entered 'None (0)'	System	09 Sep 2020 03:16:55
	System	09 Sep 2020 03:16:55

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:54:48

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T22:16:31', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '025038cf-6015-471d-92d5-06751ed3662a' User entered 'None (0)'	System	09 Sep 2020 03:16:55
	System	09 Sep 2020 03:16:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T22:16:34', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '025038cf-6015-471d-92d5-06751ed3662a' User entered 'None (0)'	System	09 Sep 2020 03:16:55
	System	09 Sep 2020 03:16:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T22:16:35', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '025038cf-6015-471d-92d5-06751ed3662a' User entered 'None (0)'	System	09 Sep 2020 03:16:55
	System	09 Sep 2020 03:16:55

US3812081

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:54:48

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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T22:16:38', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '025038cf-6015-471d-92d5-06751ed3662a' User entered 'No (N)'	System	09 Sep 2020 03:16:55
	System	09 Sep 2020 03:16:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-09-08T22:16:53', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '025038cf-6015-471d-92d5-06751ed3662a' User entered '08 Sep 2020 22:16'	System	09 Sep 2020 03:16:55
	System	09 Sep 2020 03:16:55



**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:54:48**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 22:45:55

**US3812081**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Yes (Y)'	Karen Knapp (b) (4)	09 Sep 2020 19:59:22
	(b) (4)	

US3812081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '9 Sep 2020'	Karen Knapp (b) (4)	09 Sep 2020 19:59:22
	(b) (4)	

US3812081

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	09 Sep 2020 19:59:22
	(b) (4)	

**US3812081**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered empty.	Karen Knapp (b) (4)	09 Sep 2020 19:59:22
	(b) (4)	

US3812081

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Yes (Y)'	Karen Knapp (b) (4)	09 Sep 2020 19:59:28
	(b) (4)	

US3812081

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'I'	System	09 Sep 2020 19:59:28



US3812081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:48

Was Contact Attempted?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	17 Sep 2020 14:49:02
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	17 Sep 2020 14:48:41
User entered 'Yes (Y)'	Karen Knapp (b) (4)	17 Sep 2020 14:48:41
	(b) (4)	

US3812081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '17 Sep 2020'	Karen Knapp (b) (4)	17 Sep 2020 14:48:41
	(b) (4)	

US3812081

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	17 Sep 2020 14:49:02
reason for change: Data Entry Error	(b) (4)	
User entered empty.	Karen Knapp (b) (4)	17 Sep 2020 14:48:41
	(b) (4)	

**US3812081**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered empty.	Karen Knapp (b) (4)	17 Sep 2020 14:48:41
	(b) (4)	

US3812081

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Yes (Y)'	Karen Knapp (b) (4)	17 Sep 2020 14:49:08
	(b) (4)	

US3812081

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:48

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'I'	System	17 Sep 2020 14:49:08

US3812081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:48

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Yes (Y)'	Karen Knapp (b) (4)	23 Sep 2020 22:01:59
	(b) (4)	

US3812081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '23 Sep 2020'	Karen Knapp (b) (4)	23 Sep 2020 22:01:59
	(b) (4)	



US3812081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:48

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	23 Sep 2020 22:01:59
	(b) (4)	

US3812081

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered empty.	Karen Knapp (b) (4)	23 Sep 2020 22:01:59
	(b) (4)	

US3812081

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Yes (Y)'	Karen Knapp (b) (4)	23 Sep 2020 22:02:03
	(b) (4)	

**US3812081**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:54:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'I'	System	23 Sep 2020 22:02:03

**US3812081**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:54:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	19 Oct 2020 20:09:01
	(b) (4)	

**US3812081**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:54:48**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '1 Oct 2020'	Breanna Galibert (b) (4)	19 Oct 2020 20:09:01
	(b) (4)	

US3812081

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	19 Oct 2020 20:09:01
	(b) (4)	

**US3812081**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:54:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'VISIT3'	System	19 Oct 2020 20:09:01



US3812081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	19 Oct 2020 20:09:20
	(b) (4)	

US3812081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '1 Oct 2020'	Breanna Galibert (b) (4)	19 Oct 2020 20:09:20
	(b) (4)	

US3812081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '16:05'	Breanna Galibert (b) (4)	19 Oct 2020 20:09:20
	(b) (4)	

**US3812081**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered '1 Oct 2020 16:05'	System	19 Oct 2020 20:09:20

US3812081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	23 Oct 2020 15:00:22
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.'	Angie Kean (b) (4)	20 Oct 2020 22:49:09
answered with 'NCS' (Site from System).	(b) (4)	
User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	19 Oct 2020 20:09:20
User entered '96.7' F	Breanna Galibert (b) (4)	19 Oct 2020 20:09:20
	(b) (4)	

US3812081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	19 Oct 2020 20:09:20
	(b) (4)	

US3812081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	19 Oct 2020 20:09:20
	(b) (4)	

US3812081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '60'	Breanna Galibert (b) (4)	19 Oct 2020 20:09:20
	(b) (4)	



**US3812081**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'bpm'	System	19 Oct 2020 20:09:20

US3812081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '12'	Breanna Galibert (b) (4)	19 Oct 2020 20:09:20
	(b) (4)	

US3812081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'breaths/min'	System	19 Oct 2020 20:09:20

US3812081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '122'	Breanna Galibert (b) (4)	19 Oct 2020 20:09:20
	(b) (4)	

**US3812081**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'mmHg'	System	19 Oct 2020 20:09:20

US3812081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '74'	Breanna Galibert (b) (4)	19 Oct 2020 20:09:20
	(b) (4)	

**US3812081**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'mmHg'	System	19 Oct 2020 20:09:20

US3812081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21



US3812081

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21

US3812081

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:48

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	19 Oct 2020 20:09:31
	(b) (4)	

US3812081

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:48

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	19 Oct 2020 20:09:31
	(b) (4)	

US3812081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	19 Oct 2020 20:09:43
	(b) (4)	

US3812081

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '1 Oct 2020'	Breanna Galibert (b) (4)	19 Oct 2020 20:09:43
	(b) (4)	

**US3812081**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:54:48**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '16:15'	Breanna Galibert (b) (4)	19 Oct 2020 20:09:43
	(b) (4)	

**US3812081**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:54:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered '1 Oct 2020 16:15'	System	19 Oct 2020 20:09:43

US3812081

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Yes (Y)'	Karen Knapp (b) (4)	24 Oct 2020 17:48:12
	(b) (4)	



**US3812081**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:54:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:47:21
User entered 'I'	System	24 Oct 2020 17:48:12

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 64'	System	07 Aug 2020 22:19:27

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-10-07T08:11:25', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'a0c9ec15-2943-4f5e-a7c9-ada0752f90dc'	System	07 Oct 2020 13:11:39
User entered 'No (N)'	System	07 Oct 2020 13:11:39

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Have you been exposed to someone with 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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-10-07T08:11:33', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'a0c9ec15-2943-4f5e-a7c9-ada0752f90dc'	System	07 Oct 2020 13:11:39
User entered 'No (N)'	System	07 Oct 2020 13:11:39

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-10-07T08:11:38', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'a0c9ec15-2943-4f5e-a7c9-ada0752f90dc' User entered '07 Oct 2020 08:11:38'	System	07 Oct 2020 13:11:39
	System	07 Oct 2020 13:11:39

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered '07 Oct 2020 00:01'	System	07 Aug 2020 22:19:27

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered '11 Oct 2020 23:59'	System	07 Aug 2020 22:19:27

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 71'	System	07 Aug 2020 22:19:27



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-10-14T16:56:05', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '96bd5d0f-92a0-40f8-8710-6b67e3cf88ff'	System	14 Oct 2020 21:56:22
User entered 'No (N)'	System	14 Oct 2020 21:56:22

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Have you been exposed to someone with 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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-10-14T16:56:13', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '96bd5d0f-92a0-40f8-8710-6b67e3cf88ff'	System	14 Oct 2020 21:56:22
User entered 'No (N)'	System	14 Oct 2020 21:56:22

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-10-14T16:56:18', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '96bd5d0f-92a0-40f8-8710-6b67e3cf88ff' User entered '14 Oct 2020 16:56:18'	System	14 Oct 2020 21:56:22
	System	14 Oct 2020 21:56:22

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered '14 Oct 2020 00:01'	System	07 Aug 2020 22:19:27

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered '18 Oct 2020 23:59'	System	07 Aug 2020 22:19:27

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 78'	System	07 Aug 2020 22:19:27

US3812081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

[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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-10-21T14:16:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '34708f02-9aa9-4c99-b766-8be5af88d083'	System	21 Oct 2020 19:16:15
User entered 'No (N)'	System	21 Oct 2020 19:16:15

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Have you been exposed to someone with 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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-10-21T14:16:06', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '34708f02-9aa9-4c99-b766-8be5af88d083'	System	21 Oct 2020 19:16:15
User entered 'No (N)'	System	21 Oct 2020 19:16:15



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-10-21T14:16:11', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '34708f02-9aa9-4c99-b766-8be5af88d083' User entered '21 Oct 2020 14:16:11'	System	21 Oct 2020 19:16:15
	System	21 Oct 2020 19:16:15

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered '21 Oct 2020 00:01'	System	07 Aug 2020 22:19:27

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered '25 Oct 2020 23:59'	System	07 Aug 2020 22:19:27

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 92'	System	07 Aug 2020 22:19:27

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-11-04T03:24:28', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '6c0217d2-445b-4b80-bfd4-79f2b4dc8217' User entered 'No (N)'	System	04 Nov 2020 09:24:52
	System	04 Nov 2020 09:24:52

US3812081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

Have you been exposed to someone with 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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-11-04T03:24:42', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '6c0217d2-445b-4b80-bfd4-79f2b4dc8217' User entered 'No (N)'	System	04 Nov 2020 09:24:52
	System	04 Nov 2020 09:24:52

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-11-04T03:24:47', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '6c0217d2-445b-4b80-bfd4-79f2b4dc8217' User entered '04 Nov 2020 03:24:47'	System	04 Nov 2020 09:24:52
	System	04 Nov 2020 09:24:52

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered '04 Nov 2020 00:01'	System	07 Aug 2020 22:19:27



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered '08 Nov 2020 23:59'	System	07 Aug 2020 22:19:27

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 99'	System	07 Aug 2020 22:19:27

US3812081

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:54:48

[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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-11-11T05:32:01', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'a24993ee-e1d3-4145-bd3f-2c68d2a0e0b2'	System	11 Nov 2020 11:32:15
User entered 'No (N)'	System	11 Nov 2020 11:32:15

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Have you been exposed to someone with 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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-11-11T05:32:08', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'a24993ee-e1d3-4145-bd3f-2c68d2a0e0b2'	System	11 Nov 2020 11:32:15
User entered 'No (N)'	System	11 Nov 2020 11:32:15

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-11-11T05:32:11', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'a24993ee-e1d3-4145-bd3f-2c68d2a0e0b2'	System	11 Nov 2020 11:32:15
User entered '11 Nov 2020 05:32:11'	System	11 Nov 2020 11:32:15

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered '11 Nov 2020 00:01'	System	07 Aug 2020 22:19:27

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered '15 Nov 2020 23:59'	System	07 Aug 2020 22:19:27

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered 'Day 106'	System	07 Aug 2020 22:19:27



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-11-18T04:41:54', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '80ad777c-5bdf-40e8-a1c8-d5a73644d1fe' User entered 'No (N)'	System	18 Nov 2020 10:42:08
	System	18 Nov 2020 10:42:08

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Have you been exposed to someone with 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)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-11-18T04:42:02', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '80ad777c-5bdf-40e8-a1c8-d5a73644d1fe'	System	18 Nov 2020 10:42:08
User entered 'No (N)'	System	18 Nov 2020 10:42:08

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (D3DE3BA5-553E-4F80-8AB2-268BA75863A8)', Time: '2020-11-18T04:42:06', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '80ad777c-5bdf-40e8-a1c8-d5a73644d1fe' User entered '18 Nov 2020 04:42:06'	System	18 Nov 2020 10:42:08
	System	18 Nov 2020 10:42:08

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered '18 Nov 2020 00:01'	System	07 Aug 2020 22:19:27

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:42:33
Data entry locked.	System	07 Aug 2020 22:19:27
User entered '22 Nov 2020 23:59'	System	07 Aug 2020 22:19:27

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2020-11-23T15:40:28', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '8eef3881-eb35-47eb-9777-af755c81e4e1' User entered 'No (N)'	System	23 Nov 2020 21:40:43

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2020-11-23T15:40:37', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '8eef3881-eb35-47eb-9777-af755c81e4e1'	System	23 Nov 2020 21:40:43
User entered 'No (N)'	System	23 Nov 2020 21:40:43



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2020-11-23T15:40:40', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '8eef3881-eb35-47eb-9777-af755c81e4e1' User entered '23 Nov 2020 15:40:40'	System	23 Nov 2020 21:40:43
	System	23 Nov 2020 21:40:43

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2020-11-30T11:32:25', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '512b7601-5d6b-433b-a44d-790ac6964954'	System	30 Nov 2020 17:32:57
User entered 'No (N)'	System	30 Nov 2020 17:32:57

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2020-11-30T11:32:45', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '512b7601-5d6b-433b-a44d-790ac6964954'	System	30 Nov 2020 17:32:57
User entered 'No (N)'	System	30 Nov 2020 17:32:57

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2020-11-30T11:32:55', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '512b7601-5d6b-433b-a44d-790ac6964954' User entered '30 Nov 2020 11:32:55'	System	30 Nov 2020 17:32:57
	System	30 Nov 2020 17:32:57

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 16:24:07



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2020-12-06T08:55:37', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '666f2411-34f2-4356-8881-02477433cda9' User entered 'No (N)'	System	06 Dec 2020 14:55:55
	System	06 Dec 2020 14:55:55

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2020-12-06T08:55:39', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '666f2411-34f2-4356-8881-02477433cda9' User entered 'No (N)'	System	06 Dec 2020 14:55:55
	System	06 Dec 2020 14:55:55

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2020-12-06T08:55:53', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '666f2411-34f2-4356-8881-02477433cda9' User entered '06 Dec 2020 08:55:53'	System	06 Dec 2020 14:55:55
	System	06 Dec 2020 14:55:55

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:24:07



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2020-12-14T06:48:23', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '421b968e-0e75-4f87-ac28-e4bc4607325b' User entered 'No (N)'	System	14 Dec 2020 12:48:33
	System	14 Dec 2020 12:48:33

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2020-12-14T06:48:26', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '421b968e-0e75-4f87-ac28-e4bc4607325b' User entered 'No (N)'	System	14 Dec 2020 12:48:33
	System	14 Dec 2020 12:48:33

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2020-12-14T06:48:30', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '421b968e-0e75-4f87-ac28-e4bc4607325b' User entered '14 Dec 2020 06:48:30'	System	14 Dec 2020 12:48:33
	System	14 Dec 2020 12:48:33

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2020-12-21T22:56:56', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '03289886-2606-4846-9eff-0c752e7f5058' User entered 'No (N)'	System	22 Dec 2020 04:57:10
	System	22 Dec 2020 04:57:10

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2020-12-21T22:57:02', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '03289886-2606-4846-9eff-0c752e7f5058'	System	22 Dec 2020 04:57:10
User entered 'No (N)'	System	22 Dec 2020 04:57:10



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2020-12-21T22:57:08', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '03289886-2606-4846-9eff-0c752e7f5058'	System	22 Dec 2020 04:57:10
User entered '21 Dec 2020 22:57:08'	System	22 Dec 2020 04:57:10

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2020-12-28T10:54:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b337b7a3-d014-4969-82ea-b99ec0385121' User entered 'No (N)'	System	28 Dec 2020 16:54:09
	System	28 Dec 2020 16:54:09

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2020-12-28T10:54:03', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b337b7a3-d014-4969-82ea-b99ec0385121'	System	28 Dec 2020 16:54:09
User entered 'No (N)'	System	28 Dec 2020 16:54:09

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2020-12-28T10:54:06', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'b337b7a3-d014-4969-82ea-b99ec0385121' User entered '28 Dec 2020 10:54:06'	System	28 Dec 2020 16:54:09
	System	28 Dec 2020 16:54:09

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 16:24:07



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-01-04T19:04:13', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '2f70e581-3f85-40fd-92e9-48a0cf473f2b' User entered 'No (N)'	System	05 Jan 2021 01:04:24
	System	05 Jan 2021 01:04:24

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-01-04T19:04:16', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '2f70e581-3f85-40fd-92e9-48a0cf473f2b' User entered 'No (N)'	System	05 Jan 2021 01:04:24
	System	05 Jan 2021 01:04:24

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-01-04T19:04:19', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '2f70e581-3f85-40fd-92e9-48a0cf473f2b' User entered '04 Jan 2021 19:04:19'	System	05 Jan 2021 01:04:24
	System	05 Jan 2021 01:04:24

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:24:07



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-01-10T23:09:40', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'a5a85f65-8842-4c4b-871e-2fabefe17901'	System	11 Jan 2021 05:09:50
User entered 'No (N)'	System	11 Jan 2021 05:09:50

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-01-10T23:09:41', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'a5a85f65-8842-4c4b-871e-2fabefe17901'	System	11 Jan 2021 05:09:50
User entered 'No (N)'	System	11 Jan 2021 05:09:50

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-01-10T23:09:45', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'a5a85f65-8842-4c4b-871e-2fabefe17901' User entered '10 Jan 2021 23:09:45'	System	11 Jan 2021 05:09:50
	System	11 Jan 2021 05:09:50

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-01-17T08:23:26', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '13886f55-f0d9-4f6c-878e-1a7a250fb4bd' User entered 'No (N)'	System	17 Jan 2021 14:23:40
	System	17 Jan 2021 14:23:40

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-01-17T08:23:34', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '13886f55-f0d9-4f6c-878e-1a7a250fb4bd'	System	17 Jan 2021 14:23:40
User entered 'No (N)'	System	17 Jan 2021 14:23:40



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-01-17T08:23:37', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '13886f55-f0d9-4f6c-878e-1a7a250fb4bd' User entered '17 Jan 2021 08:23:37'	System	17 Jan 2021 14:23:40
	System	17 Jan 2021 14:23:40

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-01-27T10:55:25', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '00eae7b5-e91b-492e-aefb-a72eb8bbca0e' User entered 'No (N)'	System	27 Jan 2021 16:55:37
	System	27 Jan 2021 16:55:37

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-01-27T10:55:28', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '00eae7b5-e91b-492e-aefb-a72eb8bbca0e' User entered 'No (N)'	System	27 Jan 2021 16:55:37

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-01-27T10:55:30', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '00eae7b5-e91b-492e-aefb-a72eb8bbca0e' User entered '27 Jan 2021 10:55:30'	System	27 Jan 2021 16:55:37

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 16:24:07



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-02-03T09:24:45', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f1a9f306-44b8-4f6f-82ee-53026a493f04' User entered 'No (N)'	System	03 Feb 2021 15:24:53
	System	03 Feb 2021 15:24:53

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-02-03T09:24:48', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f1a9f306-44b8-4f6f-82ee-53026a493f04'	System	03 Feb 2021 15:24:53
User entered 'No (N)'	System	03 Feb 2021 15:24:53

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-02-03T09:24:50', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f1a9f306-44b8-4f6f-82ee-53026a493f04' User entered '03 Feb 2021 09:24:50'	System	03 Feb 2021 15:24:53
	System	03 Feb 2021 15:24:53

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:24:07



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-02-07T07:25:40', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '77c680dd-c582-46ff-b15a-b8bdaf20212b' User entered 'No (N)'	System	07 Feb 2021 13:25:49
	System	07 Feb 2021 13:25:49

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-02-07T07:25:43', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '77c680dd-c582-46ff-b15a-b8bdaf20212b' User entered 'No (N)'	System	07 Feb 2021 13:25:49

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-02-07T07:25:46', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '77c680dd-c582-46ff-b15a-b8bdaf20212b' User entered '07 Feb 2021 07:25:46'	System	07 Feb 2021 13:25:49
	System	07 Feb 2021 13:25:49

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-02-14T07:14:39', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '547e258b-f685-42b7-b3cb-02ebdb0a28ca' User entered 'No (N)'	System	14 Feb 2021 13:14:48
	System	14 Feb 2021 13:14:48

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-02-14T07:14:43', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '547e258b-f685-42b7-b3cb-02ebdb0a28ca' User entered 'No (N)'	System	14 Feb 2021 13:14:48



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-02-14T07:14:45', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '547e258b-f685-42b7-b3cb-02ebdb0a28ca' User entered '14 Feb 2021 07:14:45'	System	14 Feb 2021 13:14:48
	System	14 Feb 2021 13:14:48

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-02-21T20:35:19', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'ece8891c-e610-4cec-acec-488045962ecd' User entered 'No (N)'	System	22 Feb 2021 02:35:39
	System	22 Feb 2021 02:35:39

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-02-21T20:35:23', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'ece8891c-e610-4cec-acec-488045962ecd' User entered 'No (N)'	System	22 Feb 2021 02:35:39

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-02-21T20:35:27', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'ece8891c-e610-4cec-acec-488045962ecd' User entered '21 Feb 2021 20:35:27'	System	22 Feb 2021 02:35:39

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 16:24:07



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-02-28T00:02:02-06:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '74c50d6f-9ba1-4308-a9c5-e4f5179f109b'	System	28 Feb 2021 06:02:43
User entered 'No (N)'	System	28 Feb 2021 06:02:43

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-02-28T00:02:07-06:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '74c50d6f-9ba1-4308-a9c5-e4f5179f109b' User entered 'No (N)'	System	28 Feb 2021 06:02:43
	System	28 Feb 2021 06:02:43

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-02-28T00:02:10-06:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '74c50d6f-9ba1-4308-a9c5-e4f5179f109b' User entered '28 Feb 2021 06:02:10'	System	28 Feb 2021 06:02:43
	System	28 Feb 2021 06:02:43

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:24:07



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-03-07T01:40:11-06:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '600a05e8-fecd-4c75-8700-f97105500299'	System	07 Mar 2021 07:40:20
User entered 'No (N)'	System	07 Mar 2021 07:40:20

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-03-07T01:40:14-06:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '600a05e8-fecd-4c75-8700-f97105500299'	System	07 Mar 2021 07:40:20
User entered 'No (N)'	System	07 Mar 2021 07:40:20

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-03-07T01:40:18-06:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '600a05e8-fecd-4c75-8700-f97105500299'	System	07 Mar 2021 07:40:20
User entered '07 Mar 2021 01:40:18'	System	07 Mar 2021 07:40:20

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-03-15T06:49:00-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '43dd2026-da3d-4c04-9f44-514a1030cc01'	System	15 Mar 2021 11:49:09
User entered 'No (N)'	System	15 Mar 2021 11:49:09

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-03-15T06:49:03-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '43dd2026-da3d-4c04-9f44-514a1030cc01'	System	15 Mar 2021 11:49:09
User entered 'No (N)'	System	15 Mar 2021 11:49:09



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-03-15T06:49:06-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '43dd2026-da3d-4c04-9f44-514a1030cc01'	System	15 Mar 2021 11:49:09
User entered '15 Mar 2021 06:49:06'	System	15 Mar 2021 11:49:09

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-03-24T13:21:14-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f1395d4d-e504-426e-b6de-5f7d8df77fbe'	System	24 Mar 2021 18:21:26
User entered 'No (N)'	System	24 Mar 2021 18:21:26

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-03-24T13:21:19-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f1395d4d-e504-426e-b6de-5f7d8df77fbe'	System	24 Mar 2021 18:21:26
User entered 'No (N)'	System	24 Mar 2021 18:21:26

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-03-24T13:21:22-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'f1395d4d-e504-426e-b6de-5f7d8df77fbe' User entered '24 Mar 2021 13:21:22'	System	24 Mar 2021 18:21:26
	System	24 Mar 2021 18:21:26

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 16:24:07



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-03-31T16:41:59-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '5860c567-92cb-4ed1-b0c2-88059193f21d' User entered 'Yes (Y)'	System	31 Mar 2021 21:43:13
	System	31 Mar 2021 21:43:13

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-03-31T16:42:07-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '5860c567-92cb-4ed1-b0c2-88059193f21d'	System	31 Mar 2021 21:43:13
User entered 'No (N)'	System	31 Mar 2021 21:43:13

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-03-31T16:42:17-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '5860c567-92cb-4ed1-b0c2-88059193f21d' User entered 'No (N)'	System	31 Mar 2021 21:43:13
	System	31 Mar 2021 21:43:13

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-03-31T16:42:32-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '5860c567-92cb-4ed1-b0c2-88059193f21d' User entered 'Yes (Y)'	System	31 Mar 2021 21:43:13
	System	31 Mar 2021 21:43:13

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-03-31T16:42:42-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '5860c567-92cb-4ed1-b0c2-88059193f21d'	System	31 Mar 2021 21:43:13
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Mar 2021 21:43:13

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-03-31T16:42:45-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '5860c567-92cb-4ed1-b0c2-88059193f21d' User entered '31 Mar 2021 16:42:45'	System	31 Mar 2021 21:43:13
	System	31 Mar 2021 21:43:13



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-04-04T00:17:57-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'bafc9795-efaa-43c5-b447-162f0091c87d' User entered 'No (N)'	System	04 Apr 2021 05:18:08

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-04-04T00:18:02-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'bafc9795-efaa-43c5-b447-162f0091c87d'	System	04 Apr 2021 05:18:08
User entered 'No (N)'	System	04 Apr 2021 05:18:08

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-04-04T00:18:04-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: 'bafc9795-efaa-43c5-b447-162f0091c87d' User entered '04 Apr 2021 00:18:04'	System	04 Apr 2021 05:18:08
	System	04 Apr 2021 05:18:08

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 16:24:07



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-04-12T11:12:59-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '953784bb-52c4-4996-a518-30d52439642d'	System	12 Apr 2021 16:17:04
User entered 'No (N)'	System	12 Apr 2021 16:17:04

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-04-12T11:13:04-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '953784bb-52c4-4996-a518-30d52439642d'	System	12 Apr 2021 16:17:04
User entered 'No (N)'	System	12 Apr 2021 16:17:04

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-04-12T11:13:08-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '953784bb-52c4-4996-a518-30d52439642d'	System	12 Apr 2021 16:17:04
User entered '12 Apr 2021 11:13:08'	System	12 Apr 2021 16:17:04

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-04-19T21:39:59-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '4d661aa4-774d-499e-b4c6-fa72564921f4'	System	20 Apr 2021 02:40:09
User entered 'No (N)'	System	20 Apr 2021 02:40:09



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-04-19T21:40:03-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '4d661aa4-774d-499e-b4c6-fa72564921f4'	System	20 Apr 2021 02:40:09
User entered 'No (N)'	System	20 Apr 2021 02:40:09

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-04-19T21:40:06-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '4d661aa4-774d-499e-b4c6-fa72564921f4'	System	20 Apr 2021 02:40:09
User entered '19 Apr 2021 21:40:06'	System	20 Apr 2021 02:40:09

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-04-25T06:35:12-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '793749c2-856e-4dec-9bdd-3662748332e1' User entered 'No (N)'	System	25 Apr 2021 11:35:28
	System	25 Apr 2021 11:35:28

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

Have you been exposed to someone with 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 (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-04-25T06:35:21-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '793749c2-856e-4dec-9bdd-3662748332e1'	System	25 Apr 2021 11:35:28
User entered 'No (N)'	System	25 Apr 2021 11:35:28

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-04-25T06:35:24-05:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '793749c2-856e-4dec-9bdd-3662748332e1'	System	25 Apr 2021 11:35:28
User entered '25 Apr 2021 06:35:24'	System	25 Apr 2021 11:35:28



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 16:24:07



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 16:24:07



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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:24:07



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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 16:24:07



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 16:24:07



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:24:07



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 16:24:07



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:24:07

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 16:24:07



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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:24:07



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 16:24:07



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 16:24:07



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:24:07



**US3812081**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 16:24:07



**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 16:24:07



**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:24:07



**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 16:24:07



**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 16:24:07



**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:24:07



**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 16:24:07



**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 16:24:07



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:24:07



**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 16:24:07



**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 16:24:07

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 16:24:07



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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:24:07



**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 16:24:07

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 16:24:07



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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:24:07

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**Folder: New Safety Follow Up Diary (1)**

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**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 16:24:07

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 16:24:07

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:24:07

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**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 16:24:07



**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:24:07



**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 16:24:07



**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '09 Oct 2022 00:01'	System	19 Nov 2020 16:24:07

**US3812081**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:54:48**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:24:07
Amendment Manager: User entered '13 Oct 2022 23:59'	System	19 Nov 2020 16:24:07

US3812081

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:54:48**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-02-28T00:01:46-06:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '53135e99-306f-4571-941a-f9ed3b36bca7'	System	28 Feb 2021 06:02:15
User entered 'No (N)'	System	28 Feb 2021 06:02:15

**US3812081**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 17:25:24
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (60FC1D27-D77D-42A0-A36B-23AE66CD916F)', Time: '2021-02-28T00:01:56-06:00', User OID: 'PatientReportedOutcome (US3812081)', ODM File OID: '53135e99-306f-4571-941a-f9ed3b36bca7' User entered '28 Feb 2021 06:01:56'	System	28 Feb 2021 06:02:15
	System	28 Feb 2021 06:02:15



**US3812081**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Karen Knapp (b) (4)	28 Oct 2020 14:28:44

**US3812081**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '28 Oct 2020'	Karen Knapp (b) (4)	28 Oct 2020 14:28:44

**US3812081**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	28 Oct 2020 14:28:44

**US3812081**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Karen Knapp (b) (4)	28 Oct 2020 14:28:44

**US3812081**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:54:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Karen Knapp (b) (4)	28 Oct 2020 14:28:48

**US3812081**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:54:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:21:40
User entered 'I'	System	28 Oct 2020 14:28:48

**US3812081**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Karen Knapp (b) (4)	01 Dec 2020 19:44:12

**US3812081**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '1 Dec 2020'	Karen Knapp (b) (4)	01 Dec 2020 19:44:12



**US3812081**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	01 Dec 2020 19:44:12

**US3812081**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Karen Knapp (b) (4)	01 Dec 2020 19:44:12

**US3812081**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:54:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Karen Knapp (b) (4)	01 Dec 2020 19:44:16

**US3812081**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:54:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:37
User entered 'I'	System	01 Dec 2020 19:44:16

**US3812081**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Karen Knapp (b) (4)	29 Dec 2020 15:14:51

**US3812081**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '29 Dec 2020'	Karen Knapp (b) (4)	29 Dec 2020 15:14:51

**US3812081**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	29 Dec 2020 15:14:51

**US3812081**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Karen Knapp (b) (4)	29 Dec 2020 15:14:51



**US3812081**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:54:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Karen Knapp (b) (4)	29 Dec 2020 15:14:55

**US3812081**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:54:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:37
User entered 'I'	System	29 Dec 2020 15:14:55

**US3812081**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Karen Knapp (b) (4)	29 Jan 2021 21:16:22

**US3812081**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered '29 Jan 2021'	Karen Knapp (b) (4)	29 Jan 2021 21:16:22

**US3812081**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	29 Jan 2021 21:16:22

**US3812081**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered empty.	Karen Knapp (b) (4)	29 Jan 2021 21:16:22

**US3812081**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:54:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Yes (Y)'	Karen Knapp (b) (4)	29 Jan 2021 21:16:26

**US3812081**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:54:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:37
User entered 'I'	System	29 Jan 2021 21:16:26



**US3812081**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:54:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	04 Mar 2021 20:15:03

**US3812081**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:54:48**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered '03 Mar 2021'	Breanna Galibert (b) (4)	04 Mar 2021 20:15:03

US3812081

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:54:48

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	04 Mar 2021 20:15:03

**US3812081**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:54:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User entered 'VISIT4'	System	04 Mar 2021 20:15:03

US3812081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered 'No (N)'	Breanna Galibert (b) (4)	05 Apr 2021 16:14:47

US3812081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered empty.	Breanna Galibert (b) (4)	05 Apr 2021 16:14:47

**US3812081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered empty.	Breanna Galibert (b) (4)	05 Apr 2021 16:14:47

**US3812081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User entered empty.	System	05 Apr 2021 16:14:47



US3812081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered empty.	Breanna Galibert (b) (4)	05 Apr 2021 16:14:47

US3812081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered empty.	Breanna Galibert (b) (4)	05 Apr 2021 16:14:47

**US3812081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered empty.	Breanna Galibert (b) (4)	05 Apr 2021 16:14:47

US3812081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered empty.	Breanna Galibert (b) (4)	05 Apr 2021 16:14:47

**US3812081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User entered empty.	System	05 Apr 2021 16:14:47

US3812081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered empty.	Breanna Galibert (b) (4)	05 Apr 2021 16:14:47

**US3812081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User entered empty.	System	05 Apr 2021 16:14:47

US3812081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered empty.	Breanna Galibert (b) (4)	05 Apr 2021 16:14:47



**US3812081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User entered empty.	System	05 Apr 2021 16:14:47

US3812081

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:54:48

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered empty.	Breanna Galibert (b) (4)	05 Apr 2021 16:14:47

**US3812081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User entered empty.	System	05 Apr 2021 16:14:47

**US3812081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56

**US3812081**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:54:48**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56

US3812081

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:48

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered 'No (N)'	Breanna Galibert (b) (4)	04 Mar 2021 20:15:06

US3812081

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:54:48

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered empty.	Breanna Galibert (b) (4)	04 Mar 2021 20:15:06

US3812081

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	04 Mar 2021 20:15:22



**US3812081**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:54:48**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered '03 Mar 2021'	Breanna Galibert (b) (4)	04 Mar 2021 20:15:22

**US3812081**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:54:48**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered '16:10'	Breanna Galibert (b) (4)	04 Mar 2021 20:15:22

**US3812081**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:54:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User entered '03 Mar 2021 16:10'	System	04 Mar 2021 20:15:22

US3812081

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	04 Mar 2021 20:14:54

**US3812081**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:54:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 11:20:56
User entered 'I'	System	04 Mar 2021 20:14:54

**US3812081**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:10
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered 'Yes (Y)'	Maureen Dempsey (b) (4)	02 Apr 2021 14:13:13

**US3812081**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:10
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered '2 Apr 2021'	Maureen Dempsey (b) (4)	02 Apr 2021 14:13:13

**US3812081**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:10
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered 'Contact Made (CONTACT MADE)'	Maureen Dempsey (b) (4)	02 Apr 2021 14:13:13



US3812081

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:48

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:10
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered empty.	Maureen Dempsey (b) (4)	02 Apr 2021 14:13:13

**US3812081**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:54:48**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:10
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered 'Yes (Y)'	Maureen Dempsey (b) (4)	02 Apr 2021 14:13:18

**US3812081**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:54:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:10
User entered 'I'	System	02 Apr 2021 14:13:18

**US3812081**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	03 May 2021 15:16:42
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 May 2021 14:24:26
	(b) (4)	

US3812081

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:54:48

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	03 May 2021 15:16:42
User entered '30 Apr 2021'	Breanna Galibert (b) (4)	03 May 2021 14:24:26
	(b) (4)	

**US3812081**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	03 May 2021 15:16:42
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4) (b) (4)	03 May 2021 14:24:26

**US3812081**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:54:48**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	03 May 2021 15:16:42
User entered empty.	Breanna Galibert (b) (4)	03 May 2021 14:24:26
	(b) (4)	

US3812081

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:54:48

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	03 May 2021 15:16:42
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 May 2021 14:24:28
	(b) (4)	



**US3812081**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:54:48**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 14:24:28

**US3812081**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 10 Jun 2021 09:54:48**

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:44:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'No (N)'	Karen Knapp (b) (4)	24 Oct 2020 17:48:23

**US3812081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:54:48**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	04 Mar 2021 20:15:40

**US3812081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:54:48**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered '03 Mar 2021'	Breanna Galibert (b) (4)	04 Mar 2021 20:15:40

**US3812081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:54:48**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	04 Mar 2021 20:15:40

**US3812081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:54:48**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User entered 'UNBLND_DECIDE'	System	04 Mar 2021 20:15:40

**US3812081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:54:48**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered '03 Mar 2021'	Breanna Galibert (b) (4)	04 Mar 2021 20:15:55

**US3812081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:54:48**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered '0'	Breanna Galibert (b) (4)	09 Mar 2021 16:10:29
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:26:13



**US3812081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:54:48**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	04 Mar 2021 20:15:55

**US3812081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:54:48**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered 'Amendment 6 or later (Amendment 6 or later)'	Breanna Galibert (b) (4)	09 Mar 2021 16:10:29
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:26:13

**US3812081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:54:48**

**Date of unblinding** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered '03 Mar 2021'	Breanna Galibert (b) (4)	04 Mar 2021 20:15:55

**US3812081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:54:48**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered 'mRNA-1273 (mRNA-1273)'	Breanna Galibert (b) (4)	04 Mar 2021 20:15:55

**US3812081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:54:48**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered 'mRNA-1273 (mRNA-1273)'	Breanna Galibert (b) (4)	04 Mar 2021 20:15:55

**US3812081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:54:48**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered 'mRNA-1273 (mRNA-1273)'	Breanna Galibert (b) (4)	04 Mar 2021 20:15:55

**US3812081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:54:48**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered 'No (N)'	Breanna Galibert (b) (4)	04 Mar 2021 20:15:55

**US3812081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:54:48**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User entered empty.	System	04 Mar 2021 20:15:55



**US3812081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:54:48**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User entered empty.	System	04 Mar 2021 20:15:55

**US3812081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:54:48**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	04 Mar 2021 20:16:03

US3812081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:54:48

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered '03 Mar 2021'	Breanna Galibert (b) (4)	04 Mar 2021 20:16:03

**US3812081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:54:48**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered '16:10'	Breanna Galibert (b) (4)	04 Mar 2021 20:16:03

**US3812081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:54:48**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User entered '03 Mar 2021 16:10'	System	04 Mar 2021 20:16:03

US3812081

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:54:48

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	04 Mar 2021 20:16:08

**US3812081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:54:48**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered '03 Mar 2021'	Breanna Galibert (b) (4)	04 Mar 2021 20:16:08

**US3812081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:54:48**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User entered '16:15'	Breanna Galibert (b) (4)	04 Mar 2021 20:16:08



**US3812081**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:54:48**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:38
User entered '03 Mar 2021 16:15'	System	04 Mar 2021 20:16:08

US3812081

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:54:48

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:01:02
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Signature has been broken.	Lyly Dang (b) (4)	02 Apr 2021 15:43:03
User entered 'Yes (Y)' reason for change: Data Entry Error	Lyly Dang (b) (4)	02 Apr 2021 15:43:03
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'No (N)'	Karen Knapp (b) (4)	03 Sep 2020 13:07:31

US3812081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:48

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:25
User entered 'USA-US111-2021-mRNA-1273-P301000014'	System	05 Apr 2021 13:29:08
User entered 'New'	(b) (4), (b) (6)	05 Apr 2021 13:29:08

US3812081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:48

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:27
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Acute appendicitis - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 21:31:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	14 Apr 2021 21:31:02
Data point term sent to Coder	System	14 Apr 2021 21:30:08
Coding entries removed.	Lyly Dang (b) (4)	14 Apr 2021 21:29:56
Signature has been broken.	Lyly Dang (b) (4)	14 Apr 2021 21:29:56
User entered 'Acute APPENDICITIS' reason for change: Data Entry Error	Lyly Dang (b) (4)	14 Apr 2021 21:29:56
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4)	02 Apr 2021 16:37:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 Apr 2021 16:37:40
Data point term sent to Coder	System	02 Apr 2021 16:37:21
User entered 'Appendicitis'	Lyly Dang (b) (4)	02 Apr 2021 16:37:04

US3812081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:48

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:39:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Apr 2021 16:39:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Lyly Dang (b) (4)	02 Apr 2021 16:39:08
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:37:04
User entered empty.	Lyly Dang (b) (4)	02 Apr 2021 16:37:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:48

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:39:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Apr 2021 16:39:08
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	02 Apr 2021 16:39:08
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:37:04
User entered empty.	Lyly Dang (b) (4)	02 Apr 2021 16:37:04

US3812081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:48

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:39:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Apr 2021 16:39:08
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	02 Apr 2021 16:39:08
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:37:04
User entered empty.	Lyly Dang (b) (4)	02 Apr 2021 16:37:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:48

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm start date of event. 29 Mar 2021 and 01 Apr 2021 dates are both mentioned in source documents' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 15:36:08
Query 'PV Query: Please confirm start date of event. 29 Mar 2021 and 01 Apr 2021 dates are both mentioned in source documents' answered with 'Start date of symptoms is 29 Mar 2021. Date of appendectomy is 01 April 2021. ' (Site from Safety).	Lyly Dang (b) (4)	14 Apr 2021 14:10:10
User opened query 'PV Query: Please confirm start date of event. 29 Mar 2021 and 01 Apr 2021 dates are both mentioned in source documents' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 15:23:02
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:39:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Apr 2021 16:39:08
User entered '29 Mar 2021' reason for change: Data Entry Error	Lyly Dang (b) (4)	02 Apr 2021 16:39:08
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:37:04
User entered empty.	Lyly Dang (b) (4)	02 Apr 2021 16:37:04



**US3812081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	08 Apr 2021 00:48:59
User entered empty.	Lyly Dang (b) (4) [REDACTED]	02 Apr 2021 16:37:04

**US3812081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:54:48**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 16:37:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:48

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:39:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Apr 2021 16:39:08
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	02 Apr 2021 16:39:08
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:37:04
User entered empty.	Lyly Dang (b) (4)	02 Apr 2021 16:37:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:48

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered '01 Apr 2021' reason for change: Data Entry Error	Lyly Dang (b) (4)	02 Apr 2021 16:39:08
User entered empty.	Lyly Dang (b) (4)	02 Apr 2021 16:37:04

**US3812081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:54:48**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	08 Apr 2021 00:48:59
User entered empty.	Lyly Dang (b) (4) [REDACTED]	02 Apr 2021 16:37:04

**US3812081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:54:48**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Apr 2021 16:37:04

US3812081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:48

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:39:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Apr 2021 16:39:08
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Lyly Dang (b) (4)	02 Apr 2021 16:39:08
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:37:04
User entered empty.	Lyly Dang (b) (4)	02 Apr 2021 16:37:04

US3812081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:48

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'PV Query Urgent: It was reported that the subject was not hospitalized overnight. Please confirm if the event would still be considered an SAE. If yes, please provide the updated seriousness criteria as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:18:13
Query 'PV Query Urgent: It was reported that the subject was not hospitalized overnight. Please confirm if the event would still be considered an SAE. If yes, please provide the updated seriousness criteria as soon as possible.' answered with 'Subject was hospitalized overnight' (Site from Safety).	Lyly Dang (b) (4)	23 Apr 2021 21:51:56
User opened query 'PV Query Urgent: It was reported that the subject was not hospitalized overnight. Please confirm if the event would still be considered an SAE. If yes, please provide the updated seriousness criteria as soon as possible.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 14:52:26
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:39:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Apr 2021 16:39:08
User entered 'Yes (Y)' reason for change: Data Entry Error	Lyly Dang (b) (4)	02 Apr 2021 16:39:08
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:37:04
User entered empty.	Lyly Dang (b) (4)	02 Apr 2021 16:37:04



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**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	08 Apr 2021 00:48:59
User entered '0'	Lyly Dang (b) (4) [REDACTED] [REDACTED]	02 Apr 2021 16:37:04

**US3812081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	08 Apr 2021 00:48:59
User entered '0'	Lyly Dang (b) (4) [REDACTED] [REDACTED]	02 Apr 2021 16:37:04

US3812081

Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User closed query 'Requires inpatient or prolongation System 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).		02 Apr 2021 16:39:57
Query 'Requires inpatient or prolongation of existing System 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).		02 Apr 2021 16:39:57
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	02 Apr 2021 16:39:08
User entered '1' reason for change: Data Entry Error	Lyly Dang (b) (4)	02 Apr 2021 16:39:08
User entered '0'	Lyly Dang (b) (4)	02 Apr 2021 16:37:04

US3812081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:48

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:27
Signature has been broken.	Angie Kean (b) (4)	29 Apr 2021 22:32:33
	(b) (4)	
User entered '31 Mar 2021' reason for change: New Information	Angie Kean (b) (4)	29 Apr 2021 22:32:33
	(b) (4)	
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered '1 Apr 2021' reason for change: Data Entry Error	Lyly Dang (b) (4)	02 Apr 2021 16:39:37
User entered empty.	Lyly Dang (b) (4)	02 Apr 2021 16:37:04

US3812081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:48

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered '01 Apr 2021' reason for change: Data Entry Error	Lyly Dang (b) (4)	02 Apr 2021 16:39:37
User entered empty.	Lyly Dang (b) (4)	02 Apr 2021 16:37:04

**US3812081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered 'No (N)' reason for change: Data Entry Error	Lyly Dang (b) (4)	02 Apr 2021 16:39:57
User entered empty.	Lyly Dang (b) (4)	02 Apr 2021 16:37:04

**US3812081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	08 Apr 2021 00:48:59
User entered empty.	Lyly Dang (b) (4) [REDACTED]	02 Apr 2021 16:37:04

**US3812081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	08 Apr 2021 00:48:59
User entered '0'	Lyly Dang (b) (4) [REDACTED]	02 Apr 2021 16:37:04



**US3812081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	08 Apr 2021 00:48:59
User entered '0'	Lyly Dang (b) (4) [REDACTED]	02 Apr 2021 16:37:04

**US3812081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	08 Apr 2021 00:48:59
User entered '0'	Lyly Dang (b) (4) [REDACTED]	02 Apr 2021 16:37:04

US3812081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:48

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:39:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Apr 2021 16:39:08
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Lyly Dang (b) (4)	02 Apr 2021 16:39:08
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:37:04
User entered empty.	Lyly Dang (b) (4)	02 Apr 2021 16:37:04

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:39:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Apr 2021 16:39:08
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Lyly Dang (b) (4)	02 Apr 2021 16:39:08
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:37:04
User entered empty.	Lyly Dang (b) (4)	02 Apr 2021 16:37:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:48

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:39:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Apr 2021 16:39:08
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Lyly Dang (b) (4)	02 Apr 2021 16:39:08
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:37:04
User entered empty.	Lyly Dang (b) (4)	02 Apr 2021 16:37:04

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:48

None

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Apr 2021 16:39:08
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	02 Apr 2021 16:37:04
User entered '0'	Lyly Dang (b) (4)	02 Apr 2021 16:37:04

**US3812081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered '1' reason for change: Data Entry Error	Lyly Dang (b) (4)	02 Apr 2021 16:39:08
User entered '0'	Lyly Dang (b) (4)	02 Apr 2021 16:37:04

**US3812081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered '1' reason for change: Data Entry Error	Lyly Dang (b) (4)	02 Apr 2021 16:39:08
User entered '0'	Lyly Dang (b) (4)	02 Apr 2021 16:37:04



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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:39:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Apr 2021 16:39:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Lyly Dang (b) (4)	02 Apr 2021 16:39:08
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Apr 2021 16:37:04
User entered empty.	Lyly Dang (b) (4)	02 Apr 2021 16:37:04

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**Folder: Adverse Events**

**Form: Adverse Events (1)**

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	08 Apr 2021 00:48:59
User entered empty.	Lyly Dang (b) (4) [REDACTED]	02 Apr 2021 16:37:04

US3812081

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:48

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Re-Query Urgent: It was reported that the subject was not hospitalized overnight. Admission and discharge dates are 01Apr2021. It is reported that the subject went to ER on 31Mar2021. Please clarify admission date.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 14:27:21
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)	30 Apr 2021 14:27:19
User signature succeeded.	Lyly Dang (b) (4)	30 Apr 2021 02:45:27
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 'records will be submitted' (Site from Safety).	Angie Kean (b) (4)	29 Apr 2021 22:33:25
Query 'PV Re-Query Urgent: It was reported that the subject was not hospitalized overnight. Admission and discharge dates are 01Apr2021. It is reported that the subject went to ER on 31Mar2021. Please clarify admission date.' answered with 'updated to correct dates' (Site from Safety).	Angie Kean (b) (4)	29 Apr 2021 22:32:58
User opened query 'PV Re-Query Urgent: It was reported that the subject was not hospitalized overnight. Admission and discharge dates are 01Apr2021. It is reported that the subject went to ER on 31Mar2021. Please clarify admission date.' (Site from Safety).	(b) (4), (b) (6)	28 Apr 2021 20:42:25
User closed query 'PV Query: Appendectomy is mentioned as treatment for event. Please provide any further treatments/medications given for event, if applicable.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 13:18:18

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:54:48

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Appendectomy is mentioned as treatment for event. Please provide any further treatments/medications given for event, if applicable.' answered with 'updated' (Site from Safety).	Lyly Dang (b) (4)	23 Apr 2021 21:52:25
User closed query 'PV Query: Please provide information leading up to event.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 10:56:40
Query 'PV Query: Please provide information leading up to event.' answered with 'RIGHT LOWER ABDOMINAL PAIN FOR 2 DAYS, NAUSEA, AND FEVER prior to ER visit. updated' (Site from Safety).	Lyly Dang (b) (4)	20 Apr 2021 17:37:01
Signature has been broken.	Lyly Dang (b) (4)	20 Apr 2021 17:33:57
User entered 'Subject US3812081 is a 48-year-old male with a past medical history of hyperlipidemia who presented to the emergency department on 31 Mar 2021 with a chief complaint of right lower abdominal pain for 2 days, nausea, and fever. Findings from the CT scan of abdomen and pelvis were consistent with acute appendicitis without perforation. Subject underwent an urgent laparoscopic appendectomy that same day and was kept overnight for post-operative observation. Labs obtained throughout hospitalization were unremarkable and the subject's post-operative pain was well-controlled. Subject was discharged on 01 April 2021 in stable condition with the following discharge medications: Senokot-S 8.6-50 mg 2 tablets PO HS and hydrocodone/acetaminophen 5-325 mg 1 tablet PO q 4-6 hours PRN. Hospitalization records were reconciled with the subject on 15 Apr 2021. Subject denied taking any of his prescribed discharge medications and reported complete resolution of his abdominal pain. Subject denied having any post-operative complications.' reason for change: Data Entry Error	Lyly Dang (b) (4)	20 Apr 2021 17:33:57
User opened query 'PV Query: Appendectomy is mentioned as treatment for event. Please provide any further treatments/medications given for event, if applicable.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 15:27:24

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide information leading up to event.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 15:26:41
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)	12 Apr 2021 15:25:31
Query 'PV Query: Please provide information leading up to event.' canceled (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 15:25:14
User opened query 'PV Query: Please provide information leading up to event.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 15:23:43
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered 'Subject 3812081 is a 49-year-old male with a past medical history of hyperlipidemia who presented to the emergency department on 01 April 2021 with a chief complaint of abdominal pain. The subject was diagnosed with appendicitis and underwent an appendectomy on 01 April 2021. The subject was admitted for observation and was discharged the same day. Subject denied having any post-operative complications. Medical records will be requested, and SAE will be updated once additional information is obtained.' reason for change: Data Entry Error	Lyly Dang (b) (4)	02 Apr 2021 16:39:08
User entered empty.	Lyly Dang (b) (4)	02 Apr 2021 16:37:04

**US3812081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Apr 2021 16:39:08

**US3812081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 Apr 2021 16:39:08

**US3812081**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 Apr 2021 16:39:57



US3812081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:54:48

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:01:02
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 20:56:40
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2 (03SEP2020), Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (HEADACHE) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 20:08:15
Query 'Per DM CLR: Per Diary Dose 2 Day 2 (03SEP2020), Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (HEADACHE) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' answered with 'per subject this is an entry error. Subject did not take any conmeds post dose 2 for acute reactions' (Site from DM).	Anya Penly (b) (4)	19 Feb 2021 22:29:51
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2 (03SEP2020), Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Con Med recorded that matches this indication (HEADACHE) within this timeframe. Please reconcile and update the Con Med eCRF to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	31 Jan 2021 07:33:54
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 17:42:20

US3812081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	10 Aug 2020 17:44:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Aug 2020 17:44:19
Data point term sent to Coder	System	10 Aug 2020 17:43:03
User entered 'VITAMIN D'	Breanna Galibert (b) (4) (b) (4)	10 Aug 2020 17:43:01

**US3812081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 17:43:01
	(b) (4)	

US3812081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'GENERAL HEALTH'	Breanna Galibert (b) (4)	10 Aug 2020 17:43:01
	(b) (4)	

US3812081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:48

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:21
	(b) (4)	
Signature has been broken.	Lyly Dang (b) (4)	20 Apr 2021 17:43:17
	(b) (4)	
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of number of capsules as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 11:46:45
User entered '50,000' reason for change: Data Entry Error	Angie Kean (b) (4)	11 Dec 2020 01:28:52
	(b) (4)	
Query 'Per DM CLR: Please provide the actual dose for this medication instead of number of capsules as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'Updated' (Site from DM).	Angie Kean (b) (4)	11 Dec 2020 01:26:56
	(b) (4)	
User entered '1200' reason for change: Data Entry Error	Angie Kean (b) (4)	11 Dec 2020 01:26:49
	(b) (4)	
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of number of capsules as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 01:54:38
User entered '1'	Breanna Galibert (b) (4)	10 Aug 2020 17:43:01
	(b) (4)	

US3812081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'TU (IU)' reason for change: Data Entry Error	Angie Kean (b) (4)	11 Dec 2020 01:28:59
	(b) (4)	
User entered 'ug (ug)' reason for change: Data Entry Error	Angie Kean (b) (4)	11 Dec 2020 01:26:49
	(b) (4)	
User entered 'capsule (CAPSULE)' reason for change: Data Entry Error	Angie Kean (b) (4)	13 Nov 2020 19:45:33
	(b) (4)	
User entered 'Other (OTHER)'	Breanna Galibert (b) (4)	10 Aug 2020 17:43:01
	(b) (4)	

US3812081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:54:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User closed query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "tablet" or "capsule" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 19:42:09
Query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "tablet" or "capsule" from the drop down list. Please update accordingly. Else Clarify. ' answered with 'Updated' (Site from DM).	Angie Kean (b) (4) (b) (4)	13 Nov 2020 19:46:02
User entered empty; reason for change Data Entry Error	Angie Kean (b) (4) (b) (4)	13 Nov 2020 19:45:33
User opened query 'Per CDM: Per page 37 of CCGs, Select the units using the drop-down list provided. If the unit is not available from the list of choices, select 'Other', and specify in the text box provided. However the unit indicated in the other specify is one of the available option "tablet" or "capsule" from the drop down list. Please update accordingly. Else Clarify. ' (Site from DM).	(b) (4), (b) (6)	06 Nov 2020 11:53:35
User entered 'PILL'	Breanna Galibert (b) (4) (b) (4)	10 Aug 2020 17:43:01

**US3812081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'once daily (QD)'	Breanna Galibert (b) (4)	10 Aug 2020 17:43:01
	(b) (4)	



US3812081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:54:48**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 17:43:01
	(b) (4)	

**US3812081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	10 Aug 2020 17:43:01
	(b) (4)	

**US3812081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:54:48**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 17:43:01
	(b) (4)	

**US3812081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '04 Aug 2020'	Breanna Galibert (b) (4)	10 Aug 2020 17:43:01
	(b) (4)	

**US3812081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '0'	Breanna Galibert (b) (4)	10 Aug 2020 17:43:01
	(b) (4)	

**US3812081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 17:43:01
	(b) (4)	

**US3812081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:54:48**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 17:43:01
	(b) (4)	

US3812081

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 17:43:01
	(b) (4)	



**US3812081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 17:43:01

**US3812081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 17:43:01

**US3812081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 17:43:01

US3812081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:48

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
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.	(b) (4) Coder Import (b) (4) (b) (4)	02 Dec 2020 15:33:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Dec 2020 15:33:00
Data point term sent to Coder	System	02 Dec 2020 15:31:37
User entered 'Flu vaccine'	Angie Kean (b) (4) (b) (4)	02 Dec 2020 15:30:47

US3812081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:48

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Yes (Y)'	Angie Kean (b) (4)	02 Dec 2020 15:30:47
	(b) (4)	

**US3812081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'Flu prevention'	Angie Kean (b) (4)	02 Dec 2020 15:30:47
	(b) (4)	

**US3812081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '0.5'	Angie Kean (b) (4)	02 Dec 2020 15:30:47
	(b) (4)	

US3812081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:48

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'mL (mL)'	Angie Kean (b) (4)	02 Dec 2020 15:30:47
	(b) (4)	



US3812081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:48

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	02 Dec 2020 15:30:47
	(b) (4)	

US3812081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:48

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'once (ONCE)'	Angie Kean (b) (4)	02 Dec 2020 15:30:47
	(b) (4)	

US3812081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:48

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	02 Dec 2020 15:30:47
	(b) (4)	

**US3812081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Angie Kean (b) (4) (b) (4)	02 Dec 2020 15:30:47

US3812081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:48

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered empty.	Angie Kean (b) (4)	02 Dec 2020 15:30:47
	(b) (4)	

**US3812081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '07 Oct 2020'	Angie Kean (b) (4)	02 Dec 2020 15:30:47
	(b) (4)	

**US3812081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '0'	Angie Kean (b) (4)	02 Dec 2020 15:30:47
	(b) (4)	

**US3812081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	02 Dec 2020 15:30:47
	(b) (4)	



**US3812081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:54:48**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered '07 Oct 2020'	Angie Kean (b) (4)	02 Dec 2020 15:30:47
	(b) (4)	

US3812081

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:54:48

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
	(b) (4)	
User entered 'No (N)'	Angie Kean (b) (4)	02 Dec 2020 15:30:47
	(b) (4)	

**US3812081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 15:30:47

**US3812081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 15:30:47

**US3812081**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 Dec 2020 15:30:47

US3812081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:54:48

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:01:02
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Signature has been broken.	Lyly Dang (b) (4)	02 Apr 2021 19:27:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Lyly Dang (b) (4)	02 Apr 2021 19:27:53
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:38:55
User entered 'No (N)'	Karen Knapp (b) (4)	03 Sep 2020 13:07:26

US3812081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:54:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	08 Apr 2021 00:48:59
User entered '01 Apr 2021'	Lyly Dang (b) (4) [REDACTED] [REDACTED]	02 Apr 2021 19:28:29

US3812081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:54:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	14 Apr 2021 21:54:35
Signature has been broken.	Lyly Dang (b) (4)	14 Apr 2021 21:47:00
User entered 'Laparoscopic APPENDECTOMY' reason for change: Data Entry Error	Lyly Dang (b) (4)	14 Apr 2021 21:47:00
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered 'Appendectomy'	Lyly Dang (b) (4)	02 Apr 2021 19:28:29



US3812081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:54:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered 'Adverse Event (AE)'	Lyly Dang (b) (4)	02 Apr 2021 19:28:29

US3812081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:54:48

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	08 Apr 2021 00:48:59
User entered empty.	Lyly Dang (b) (4) [REDACTED] [REDACTED]	02 Apr 2021 19:28:29

US3812081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:54:48

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	14 Apr 2021 21:54:35
User entered '31 Mar 2021'	Lyly Dang (b) (4) [REDACTED] [REDACTED]	14 Apr 2021 21:54:27

US3812081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:54:48

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	14 Apr 2021 21:54:35
User entered 'CT scan of the abdomen and pelvis'	Lyly Dang (b) (4) [REDACTED]	14 Apr 2021 21:54:27

US3812081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:54:48

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	14 Apr 2021 21:54:35
User entered 'Adverse Event (AE)'	Lyly Dang (b) (4)	14 Apr 2021 21:54:27

US3812081

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:54:48

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4) [REDACTED]	14 Apr 2021 21:54:35
User entered empty.	Lyly Dang (b) (4) [REDACTED] [REDACTED]	14 Apr 2021 21:54:27

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:47
User entered 'USA-US111-2021-MRNA-1273-P301000014'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'Yes (Y)'	System	05 Apr 2021 13:29:08



**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'Yes (Y)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'lauren'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'clement'	System	05 Apr 2021 13:29:08



US3812081

Folder: SAE USA-US111-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:48

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 10:56:50
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:09
Un-reviewed for Safety.	System	15 Apr 2021 15:36:49
Signature has been broken.	System	15 Apr 2021 15:36:49
User entered empty.	System	15 Apr 2021 15:36:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered '711 Old Ballas Rd'	Breanna Galibert (b) (4)	05 Apr 2021 15:15:34

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 10:56:50
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:09
Un-reviewed for Safety.	System	15 Apr 2021 15:36:49
Signature has been broken.	System	15 Apr 2021 15:36:49
User entered empty.	System	15 Apr 2021 15:36:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered 'St. Louis'	Breanna Galibert (b) (4)	05 Apr 2021 15:15:34

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'MO'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 10:56:50
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:09
Un-reviewed for Safety.	System	15 Apr 2021 15:36:49
Signature has been broken.	System	15 Apr 2021 15:36:49
User entered empty.	System	15 Apr 2021 15:36:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered '63141'	Breanna Galibert (b) (4)	05 Apr 2021 15:15:34

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered 'US'	System	05 Apr 2021 13:30:56

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 14:27:39
User entered '4'	System	26 Apr 2021 13:03:35
User entered '3'	System	21 Apr 2021 10:57:01
User entered '2'	System	15 Apr 2021 15:36:49
User entered '1'	System	05 Apr 2021 13:30:56

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:47
User entered 'USA-US111-2021-MRNA-1273-P301000014'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'Yes (Y)'	System	05 Apr 2021 13:29:08



**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'Yes (Y)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'lauren'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'clement'	System	05 Apr 2021 13:29:08



**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 10:56:50
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:09
Un-reviewed for Safety.	System	15 Apr 2021 15:36:49
Signature has been broken.	System	15 Apr 2021 15:36:49
User entered empty.	System	15 Apr 2021 15:36:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered '711 Old Ballas Rd'	Breanna Galibert (b) (4)	05 Apr 2021 15:15:34

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 10:56:50
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:09
Un-reviewed for Safety.	System	15 Apr 2021 15:36:49
Signature has been broken.	System	15 Apr 2021 15:36:49
User entered empty.	System	15 Apr 2021 15:36:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered 'St. Louis'	Breanna Galibert (b) (4)	05 Apr 2021 15:15:34

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'MO'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 10:56:50
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:09
Un-reviewed for Safety.	System	15 Apr 2021 15:36:49
Signature has been broken.	System	15 Apr 2021 15:36:49
User entered empty.	System	15 Apr 2021 15:36:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered '63141'	Breanna Galibert (b) (4)	05 Apr 2021 15:15:34

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered 'US'	System	05 Apr 2021 13:30:56

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 14:27:39
User entered '4'	System	26 Apr 2021 13:03:35
User entered '3'	System	21 Apr 2021 10:57:01
User entered '2'	System	15 Apr 2021 15:36:49
User entered '1'	System	05 Apr 2021 13:30:56

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:54:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered '05/Apr/2021 09:30'	System	05 Apr 2021 13:30:56

US3812081

Folder: SAE USA-US111-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:54:48

**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)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered 'I'	(b) (4), (b) (6)	05 Apr 2021 13:30:56



**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:47
User entered 'USA-US111-2021-MRNA-1273-P301000014'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'Yes (Y)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'Yes (Y)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08



**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'lauren'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'clement'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 10:56:50
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:09
Un-reviewed for Safety.	System	15 Apr 2021 15:36:49
Signature has been broken.	System	15 Apr 2021 15:36:49
User entered empty.	System	15 Apr 2021 15:36:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered '711 Old Ballas Rd'	Breanna Galibert (b) (4)	05 Apr 2021 15:15:34

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 10:56:50
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:09
Un-reviewed for Safety.	System	15 Apr 2021 15:36:49
Signature has been broken.	System	15 Apr 2021 15:36:49
User entered empty.	System	15 Apr 2021 15:36:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered 'St. Louis'	Breanna Galibert (b) (4)	05 Apr 2021 15:15:34

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'MO'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 10:56:50
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:09
Un-reviewed for Safety.	System	15 Apr 2021 15:36:49
Signature has been broken.	System	15 Apr 2021 15:36:49
User entered empty.	System	15 Apr 2021 15:36:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered '63141'	Breanna Galibert (b) (4)	05 Apr 2021 15:15:34

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered 'US'	System	05 Apr 2021 13:30:56

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 14:27:39
User entered '4'	System	26 Apr 2021 13:03:35
User entered '3'	System	21 Apr 2021 10:57:01
User entered '2'	System	15 Apr 2021 15:36:49
User entered '1'	System	05 Apr 2021 13:30:56



**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:54:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:09
User entered '15/Apr/2021 11:36'	System	15 Apr 2021 15:36:49

US3812081

Folder: SAE USA-US111-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:54:48

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 10:56:50
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:09
User entered 'I'	(b) (4), (b) (6)	15 Apr 2021 15:36:49

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:47
User entered 'USA-US111-2021-MRNA-1273-P301000014'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'Yes (Y)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'Yes (Y)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08



**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'lauren'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'clement'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 10:56:50
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:09
Un-reviewed for Safety.	System	15 Apr 2021 15:36:49
Signature has been broken.	System	15 Apr 2021 15:36:49
User entered empty.	System	15 Apr 2021 15:36:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered '711 Old Ballas Rd'	Breanna Galibert (b) (4)	05 Apr 2021 15:15:34

US3812081

Folder: SAE USA-US111-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:48

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 10:56:50
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:09
Un-reviewed for Safety.	System	15 Apr 2021 15:36:49
Signature has been broken.	System	15 Apr 2021 15:36:49
User entered empty.	System	15 Apr 2021 15:36:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered 'St. Louis'	Breanna Galibert (b) (4)	05 Apr 2021 15:15:34

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'MO'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 10:56:50
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:09
Un-reviewed for Safety.	System	15 Apr 2021 15:36:49
Signature has been broken.	System	15 Apr 2021 15:36:49
User entered empty.	System	15 Apr 2021 15:36:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered '63141'	Breanna Galibert (b) (4)	05 Apr 2021 15:15:34



**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered 'US'	System	05 Apr 2021 13:30:56

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 14:27:39
User entered '4'	System	26 Apr 2021 13:03:35
User entered '3'	System	21 Apr 2021 10:57:01
User entered '2'	System	15 Apr 2021 15:36:49
User entered '1'	System	05 Apr 2021 13:30:56

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:54:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:21
User entered '21/Apr/2021 10:57'	System	21 Apr 2021 10:57:01

US3812081

Folder: SAE USA-US111-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:54:48

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	26 Apr 2021 13:03:21
User signature succeeded.	Lyly Dang (b) (4)	21 Apr 2021 14:41:21
User entered 'I'	(b) (4), (b) (6)	21 Apr 2021 10:57:01

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:47
User entered 'USA-US111-2021-MRNA-1273-P301000014'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'Yes (Y)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08



**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'Yes (Y)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'lauren'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'clement'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 10:56:50
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:09
Un-reviewed for Safety.	System	15 Apr 2021 15:36:49
Signature has been broken.	System	15 Apr 2021 15:36:49
User entered empty.	System	15 Apr 2021 15:36:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered '711 Old Ballas Rd'	Breanna Galibert (b) (4)	05 Apr 2021 15:15:34

US3812081

Folder: SAE USA-US111-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:48

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 10:56:50
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:09
Un-reviewed for Safety.	System	15 Apr 2021 15:36:49
Signature has been broken.	System	15 Apr 2021 15:36:49
User entered empty.	System	15 Apr 2021 15:36:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered 'St. Louis'	Breanna Galibert (b) (4)	05 Apr 2021 15:15:34



**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'MO'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 10:56:50
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:09
Un-reviewed for Safety.	System	15 Apr 2021 15:36:49
Signature has been broken.	System	15 Apr 2021 15:36:49
User entered empty.	System	15 Apr 2021 15:36:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered '63141'	Breanna Galibert (b) (4)	05 Apr 2021 15:15:34

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered 'US'	System	05 Apr 2021 13:30:56

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 14:27:39
User entered '4'	System	26 Apr 2021 13:03:35
User entered '3'	System	21 Apr 2021 10:57:01
User entered '2'	System	15 Apr 2021 15:36:49
User entered '1'	System	05 Apr 2021 13:30:56

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:54:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 13:34:16
User entered '26/Apr/2021 13:03'	System	26 Apr 2021 13:03:35

US3812081

Folder: SAE USA-US111-2021-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:54:48

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:27:48
User signature succeeded.	Lyly Dang (b) (4)	28 Apr 2021 13:34:16
User entered 'I'	(b) (4), (b) (6)	26 Apr 2021 13:03:35

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:47
User entered 'USA-US111-2021-MRNA-1273-P301000014'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'Yes (Y)'	System	05 Apr 2021 13:29:08



**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'Yes (Y)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'No (N)'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'lauren'	System	05 Apr 2021 13:29:08

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'clement'	System	05 Apr 2021 13:29:08



**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 10:56:50
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:09
Un-reviewed for Safety.	System	15 Apr 2021 15:36:49
Signature has been broken.	System	15 Apr 2021 15:36:49
User entered empty.	System	15 Apr 2021 15:36:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered '711 Old Ballas Rd'	Breanna Galibert (b) (4)	05 Apr 2021 15:15:34

US3812081

Folder: SAE USA-US111-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:48

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 10:56:50
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:09
Un-reviewed for Safety.	System	15 Apr 2021 15:36:49
Signature has been broken.	System	15 Apr 2021 15:36:49
User entered empty.	System	15 Apr 2021 15:36:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered 'St. Louis'	Breanna Galibert (b) (4)	05 Apr 2021 15:15:34

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
Reviewed for Safety.	(b) (4), (b) (6)	05 Apr 2021 13:30:50
User entered 'MO'	System	05 Apr 2021 13:29:08

US3812081

Folder: SAE USA-US111-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 10 Jun 2021 09:54:48

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 10:56:50
User signature succeeded.	Lyly Dang (b) (4)	15 Apr 2021 19:12:09
Un-reviewed for Safety.	System	15 Apr 2021 15:36:49
Signature has been broken.	System	15 Apr 2021 15:36:49
User entered empty.	System	15 Apr 2021 15:36:49
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered '63141'	Breanna Galibert (b) (4)	05 Apr 2021 15:15:34

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 15:36:35
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:48:59
User entered 'US'	System	05 Apr 2021 13:30:56

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:54:48**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	30 Apr 2021 14:27:39
User entered '4'	System	26 Apr 2021 13:03:35
User entered '3'	System	21 Apr 2021 10:57:01
User entered '2'	System	15 Apr 2021 15:36:49
User entered '1'	System	05 Apr 2021 13:30:56

**US3812081**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000014**

**Form: Safety Report Form (5)**

**Generated On: 10 Jun 2021 09:54:48**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	01 May 2021 20:47:47
User entered '30/Apr/2021 10:27'	System	30 Apr 2021 14:27:39

US3812081

Folder: SAE USA-US111-2021-MRNA-1273-P301000014

Form: Safety Report Form (5)

Generated On: 10 Jun 2021 09:54:48

**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.	Lyly Dang (b) (4)	01 May 2021 20:47:47
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 14:27:48
User entered 'I'	(b) (4), (b) (6)	30 Apr 2021 14:27:39