

US3812085 (Prod: Sundance Clinical Research - Platinum - PPDS)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:55:27

All time stamps listed in this document are displayed in GMT

US3812085

Form: Participant Creation

Data signed: (b) (4) 20 Feb 2021 19:39:25

Generated On: 10 Jun 2021 09:55:27

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Participant ID

US3812085

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

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US3812085

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

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

US3812085

Folder: Screening

Form: Demographics

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Date of Birth (MMM yyyy)	(b) (6) 1989
Age	31
Age Units	YEARS
Age (Derived)	31
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	False
Black	False
Asian	True
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 19:39:34

Generated On: 10 Jun 2021 09:55:27

Date of Informed Consent ( <i>dd MMM yyyy</i> )	08 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 19:39:34

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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 19:39:34

Generated On: 10 Jun 2021 09:55:27

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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) 26 Mar 2021 19:46:16

Generated On: 10 Jun 2021 09:55:27

Condition	HERPES SIMPLEX VIRUS TYPE 2
Start date (dd MMM yyyy)	UN FEB 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	FEB 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	08 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	09:21 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 09:21
Height ( <i>xxx.x</i> )	74.0 in
Weight ( <i>xxx.x</i> )	157.2 lb
BMI ( <i>xxx.x</i> )	20.22549 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input checked="" type="radio"/>
If Other, specify	ND - Not Done
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

08 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 19:39:34

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

**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 19:39:34

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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 19:39:34

Generated On: 10 Jun 2021 09:55:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	08 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 19:39:34

Generated On: 10 Jun 2021 09:55:27

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

What was the participant's randomization number? 102255

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 19:39:34

Generated On: 10 Jun 2021 09:55:27

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 19:39:34

Generated On: 10 Jun 2021 09:55:27

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)	08 AUG 2020
Time of assessment (00:00-23:59)	09:21 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 09:21
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	96 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 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 19:39:34

Generated On: 10 Jun 2021 09:55:27

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)	08 AUG 2020
Time of assessment (00:00-23:59)	10:39 (24 HR)
Vital Signs Date and Time (derived)	08 AUG 2020 10:39
Temperature (xxx.x)	97.9 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)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 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 19:39:34

Generated On: 10 Jun 2021 09:55:27

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 19:39:34

Generated On: 10 Jun 2021 09:55:27

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 10:07 (24 HR)

Treatment Date and Time (derived) 08 AUG 2020 10:07

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 19:39:34

Generated On: 10 Jun 2021 09:55:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	08 AUG 2020
Collection time (00:00-23:59)	10:00 (24 HR)
Collection date and time (derived)	08 AUG 2020 10:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Collection date (dd MMM yyyy)			08 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:02	08 AUG 2020 10:02
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

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 09:55:27

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 10:44

PC Open Date & Time

08 AUG 2020 10:27

PC Close Date & Time

08 AUG 2020 12:57

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	08 AUG 2020 14:06
PC Open Date & Time	08 AUG 2020 13:52
PC Close Date & Time	09 AUG 2020 11:59



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**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

09 AUG 2020 12:00

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**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

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

10 AUG 2020 12:00

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 AUG 2020 12:00

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:27

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**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

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Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.0 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

12 AUG 2020 12:00

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PC Open Date & Time

12 AUG 2020 12:00

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PC Close Date & Time

13 AUG 2020 11:59

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US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 12:04

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:27

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**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

---

Was **TEMPERATURE** taken?

Yes ☒

No ☐

---

Please record your **TEMPERATURE** in °F

98.1 °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

14 AUG 2020 12:00

---

PC Open Date & Time

14 AUG 2020 12:00

---

PC Close Date & Time

15 AUG 2020 11:59

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US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**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

08 AUG 2020 10:44

PC Open Date & Time

08 AUG 2020 10:27

PC Close Date & Time

08 AUG 2020 12:57

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

08 AUG 2020 14:06

PC Open Date & Time

08 AUG 2020 13:52

PC Close Date & Time

09 AUG 2020 11:59



US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 12:01

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

10 AUG 2020 12:01

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

11 AUG 2020 12:01

PC Open Date & Time

11 AUG 2020 12:00

PC Close Date & Time

12 AUG 2020 11:59

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**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 12:00

PC Open Date & Time

12 AUG 2020 12:00

PC Close Date & Time

13 AUG 2020 11:59

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 AUG 2020 12:04

PC Open Date & Time

13 AUG 2020 12:00

PC Close Date & Time

14 AUG 2020 11:59

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

14 AUG 2020 12:00

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**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 ☐

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 10:45
PC Open Date & Time	08 AUG 2020 10:27
PC Close Date & Time	08 AUG 2020 12:57



US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**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 ☐

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

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

No ☒

Yes ☐

PC Time stamp	08 AUG 2020 14:07
PC Open Date & Time	08 AUG 2020 13:52
PC Close Date & Time	09 AUG 2020 11:59

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 2

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 12:01
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 12:02
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**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 ☒

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

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



US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**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)

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Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

Yes <input type="checkbox"/>	
PC Time stamp	12 AUG 2020 12:01
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 6

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

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Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

Yes <input type="checkbox"/>	
PC Time stamp	13 AUG 2020 12:04
PC Open Date & Time	13 AUG 2020 12:00
PC Close Date & Time	14 AUG 2020 11:59

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**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 ☒

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

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

US3812085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

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*

US3812085

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3812085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812085

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812085

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 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

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

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)	02 SEP 2020
Time of assessment (00:00-23:59)	16:56 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 16:56
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	102 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

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)	02 SEP 2020
Time of assessment (00:00-23:59)	18:30 (24 HR)
Vital Signs Date and Time (derived)	02 SEP 2020 18:30
Temperature (xxx.x)	97.7 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)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3812085

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

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.*



US3812085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

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) 02 SEP 2020

What was the treatment time? (00:00-23:59) 17:57 (24 HR)

Treatment Date and Time (derived) 02 SEP 2020 17:57

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

US3812085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 SEP 2020
Collection time (00:00-23:59)	17:45 (24 HR)
Collection date and time (derived)	02 SEP 2020 17:45

US3812085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Collection date (dd MMM yyyy)			02 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	17:48	02 SEP 2020 17:48
Nasopharyngeal Swab 2	No		

US3812085

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**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

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

Yes ☐  
No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

02 SEP 2020 18:17

PC Close Date & Time

02 SEP 2020 20:47

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

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

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

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

PC Time Stamp	02 SEP 2020 22:01
PC Open Date & Time	02 SEP 2020 21:42
PC Close Date & Time	03 SEP 2020 11:59

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**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

101.7 °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

03 SEP 2020 13:28

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**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

100.0 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

04 SEP 2020 12:02

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59



US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**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

99.0 °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

05 SEP 2020 12:31

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.8 °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

06 SEP 2020 12:02

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**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

98.6 °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

07 SEP 2020 12:00

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °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

08 SEP 2020 12:02

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

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

PC Open Date & Time

02 SEP 2020 18:17

PC Close Date & Time

02 SEP 2020 20:47

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**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

02 SEP 2020 22:02

PC Open Date & Time

02 SEP 2020 21:42

PC Close Date & Time

03 SEP 2020 11:59

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

03 SEP 2020 13:29

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**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

04 SEP 2020 12:03

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59



US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**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

05 SEP 2020 12:32

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**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 12:02

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**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

07 SEP 2020 12:00

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**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 12:03

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**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 ☐

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

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

No ☐

Yes ☐

PC Time stamp

PC Open Date & Time

02 SEP 2020 18:17

PC Close Date & Time

02 SEP 2020 20:47

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**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 ☐

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

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

No ☒

Yes ☐

PC Time stamp	02 SEP 2020 22:02
PC Open Date & Time	02 SEP 2020 21:42
PC Close Date & Time	03 SEP 2020 11:59



US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**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 ☒

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 13:30
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☒

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☒

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 12:03
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**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 ☒

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 12:32
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

**DAY 5**

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 12:02
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59



US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**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 ☒

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 12:01
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

**DAY 7**

**HEADACHE**

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

**FATIGUE**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**MUSCLE ACHES ALL OVER BODY**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**JOINT ACHES IN SEVERAL JOINTS**

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

**NAUSEA/VOMITING**

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

**CHILLS**

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

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

US3812085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812085

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812085

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3812085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

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*

US3812085

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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	VISIT3

US3812085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 SEP 2020
Time of assessment (00:00-23:59)	16:14 (24 HR)
Vital Signs Date and Time (derived)	30 SEP 2020 16:14
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3812085

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

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.*

US3812085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

30 SEP 2020

Collection time (00:00-23:59)

16:25 (24 HR)

Collection date and time (derived)

30 SEP 2020 16:25

US3812085

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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

Date and time of submission

Patient Cloud Open Date & Time

08 OCT 2020 00:01

Patient Cloud Close Date & Time

12 OCT 2020 23:59

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 15 OCT 2020 00:01:31

Patient Cloud Open Date & Time 15 OCT 2020 00:01

Patient Cloud Close Date & Time 19 OCT 2020 23:59

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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	26 OCT 2020 09:23:34
Patient Cloud Open Date & Time	22 OCT 2020 00:01
Patient Cloud Close Date & Time	26 OCT 2020 23:59

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	07 NOV 2020 14:55:15
Patient Cloud Open Date & Time	05 NOV 2020 00:01
Patient Cloud Close Date & Time	09 NOV 2020 23:59

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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

12 NOV 2020 02:30:29

Patient Cloud Open Date & Time

12 NOV 2020 00:01

Patient Cloud Close Date & Time

16 NOV 2020 23:59

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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

19 NOV 2020 02:48:01

Patient Cloud Open Date & Time

19 NOV 2020 00:01

Patient Cloud Close Date & Time

23 NOV 2020 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 NOV 2020 10:55:20

Patient Cloud Open Date & Time

23 NOV 2020 00:01

Patient Cloud Close Date & Time

27 NOV 2020 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 06:07:22

Patient Cloud Open Date & Time

30 NOV 2020 00:01

Patient Cloud Close Date & Time

04 DEC 2020 23:59



US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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

07 DEC 2020 08:52:22

Patient Cloud Open Date & Time

07 DEC 2020 00:01

Patient Cloud Close Date & Time

11 DEC 2020 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 02:35:54

Patient Cloud Open Date & Time

14 DEC 2020 00:01

Patient Cloud Close Date & Time

18 DEC 2020 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 01:36:10

Patient Cloud Open Date & Time

21 DEC 2020 00:01

Patient Cloud Close Date & Time

25 DEC 2020 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 05:52:56

Patient Cloud Open Date & Time

28 DEC 2020 00:01

Patient Cloud Close Date & Time

01 JAN 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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

07 JAN 2021 12:00:47

Patient Cloud Open Date & Time

04 JAN 2021 00:01

Patient Cloud Close Date & Time

08 JAN 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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

11 JAN 2021 07:15:17

Patient Cloud Open Date & Time

11 JAN 2021 00:01

Patient Cloud Close Date & Time

15 JAN 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 11:02:35

Patient Cloud Open Date & Time

18 JAN 2021 00:01

Patient Cloud Close Date & Time

22 JAN 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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

25 JAN 2021 00:34:34

Patient Cloud Open Date & Time

25 JAN 2021 00:01

Patient Cloud Close Date & Time

29 JAN 2021 23:59



US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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

01 FEB 2021 04:48:51

Patient Cloud Open Date & Time

01 FEB 2021 00:01

Patient Cloud Close Date & Time

05 FEB 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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

11 FEB 2021 10:30:49

Patient Cloud Open Date & Time

08 FEB 2021 00:01

Patient Cloud Close Date & Time

12 FEB 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 06:25:28

Patient Cloud Open Date & Time

15 FEB 2021 00:01

Patient Cloud Close Date & Time

19 FEB 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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

22 FEB 2021 06:35:15

Patient Cloud Open Date & Time

22 FEB 2021 00:01

Patient Cloud Close Date & Time

26 FEB 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 11:32:13

Patient Cloud Open Date & Time

01 MAR 2021 00:01

Patient Cloud Close Date & Time

05 MAR 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 23:58:42

Patient Cloud Open Date & Time

08 MAR 2021 00:01

Patient Cloud Close Date & Time

12 MAR 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 MAR 2021 09:18:54

Patient Cloud Open Date & Time

15 MAR 2021 00:01

Patient Cloud Close Date & Time

19 MAR 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 MAR 2021 09:28:13

Patient Cloud Open Date & Time

22 MAR 2021 00:01

Patient Cloud Close Date & Time

26 MAR 2021 23:59



US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 05:18:46

Patient Cloud Open Date & Time

29 MAR 2021 00:01

Patient Cloud Close Date & Time

02 APR 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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

08 APR 2021 09:11:31

Patient Cloud Open Date & Time

05 APR 2021 00:01

Patient Cloud Close Date & Time

09 APR 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 05:04:43

Patient Cloud Open Date & Time

12 APR 2021 00:01

Patient Cloud Close Date & Time

16 APR 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 APR 2021 08:15:17

Patient Cloud Open Date & Time

19 APR 2021 00:01

Patient Cloud Close Date & Time

23 APR 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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

26 APR 2021 06:35:44

Patient Cloud Open Date & Time

26 APR 2021 00:01

Patient Cloud Close Date & Time

30 APR 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

07 MAY 2021 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Open Date & Time](#)

10 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

14 MAY 2021 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

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21 MAY 2021 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

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28 MAY 2021 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

[Patient Cloud Close Date & Time](#)

04 JUN 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JUN 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Open Date & Time](#)

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14 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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18 JUN 2021 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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"/>

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

25 JUN 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

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02 JUL 2021 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

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09 JUL 2021 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

[Patient Cloud Close Date & Time](#)

23 JUL 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 JUL 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Open Date & Time](#)

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02 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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06 AUG 2021 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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°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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

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13 AUG 2021 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

20 AUG 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	23 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 AUG 2021 23:59
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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

[Patient Cloud Close Date & Time](#)

03 SEP 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

10 SEP 2021 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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"/>

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

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17 SEP 2021 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

20 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

24 SEP 2021 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

01 OCT 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Open Date & Time](#)

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04 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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08 OCT 2021 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

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15 OCT 2021 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

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22 OCT 2021 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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"/>



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	25 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 OCT 2021 23:59
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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

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05 NOV 2021 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

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12 NOV 2021 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 NOV 2021 23:59
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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

[Patient Cloud Close Date & Time](#)

26 NOV 2021 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

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03 DEC 2021 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Open Date & Time](#)

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06 DEC 2021 00:01

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[Patient Cloud Close Date & Time](#)

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10 DEC 2021 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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"/>

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

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17 DEC 2021 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	20 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	24 DEC 2021 23:59
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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	27 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	31 DEC 2021 23:59
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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 516

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

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

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

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

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

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

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

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

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

07 JAN 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Open Date & Time](#)

10 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

14 JAN 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

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21 JAN 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

[Patient Cloud Close Date & Time](#)

28 JAN 2022 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

31 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

04 FEB 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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07 FEB 2022 00:01

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11 FEB 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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14 FEB 2022 00:01

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18 FEB 2022 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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25 FEB 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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04 MAR 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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11 MAR 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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



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

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Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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18 MAR 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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21 MAR 2022 00:01

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25 MAR 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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"/>

**US3812085**

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

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**Generated On: 10 Jun 2021 09:55:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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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28 MAR 2022 00:01

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01 APR 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Please contact your study clinic immediately. Click below to confirm that you have read this 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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08 APR 2022 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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"/>



**US3812085**

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

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Please contact your study clinic immediately. Click below to confirm that you have read this 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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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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"/>

**US3812085**

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

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

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22 APR 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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

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

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

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

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25 APR 2022 00:01

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29 APR 2022 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Open Date & Time](#)

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02 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 MAY 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

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13 MAY 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

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20 MAY 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Open Date & Time](#)

23 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

27 MAY 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

[Patient Cloud Close Date & Time](#)

03 JUN 2022 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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"/>



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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10 JUN 2022 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2022 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Open Date & Time](#)

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20 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 JUN 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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="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"/>

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Open Date & Time](#)

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27 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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01 JUL 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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08 JUL 2022 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

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22 JUL 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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"/>

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

[Patient Cloud Close Date & Time](#)

29 JUL 2022 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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"/>



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

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05 AUG 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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"/>

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

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12 AUG 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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"/>

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2022 23:59
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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 747

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Open Date & Time](#)

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22 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 AUG 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

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02 SEP 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	09 SEP 2022 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

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

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Open Date & Time](#)

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12 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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16 SEP 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

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23 SEP 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	30 SEP 2022 23:59

US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**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 ☐

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

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[Patient Cloud Close Date & Time](#)

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07 OCT 2022 23:59

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US3812085

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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"/>

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

US3812085

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:55:27

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		04 MAR 2021 11:31:58

US3812085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

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*

US3812085

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3812085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:39:25

Generated On: 10 Jun 2021 09:55:27

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*

US3812085

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:39:25

Generated On: 10 Jun 2021 09:55:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:39:25

Generated On: 10 Jun 2021 09:55:27

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3812085

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:39:25

Generated On: 10 Jun 2021 09:55:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

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*

US3812085

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 20 Feb 2021 19:39:34

Generated On: 10 Jun 2021 09:55:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 08 Apr 2021 00:49:09

Generated On: 10 Jun 2021 09:55:27

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

Visit date (dd MMM yyyy)	22 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3812085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 08 Apr 2021 01:26:51

Generated On: 10 Jun 2021 09:55:27

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 MAR 2021
Time of assessment (00:00-23:59)	16:31 (24 HR)
Vital Signs Date and Time (derived)	22 MAR 2021 16:31
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3812085

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Mar 2021 19:46:16

Generated On: 10 Jun 2021 09:55:27

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 MAR 2021

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

US3812085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Mar 2021 19:46:16

Generated On: 10 Jun 2021 09:55:27

Was the sample collected? Yes ☒  
No ☐

Collection date (dd MMM yyyy) 22 MAR 2021

Collection time (00:00-23:59) 16:45 (24 HR)

Collection date and time (derived) 22 MAR 2021 16:45

US3812085

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 26 Mar 2021 19:46:16

Generated On: 10 Jun 2021 09:55:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 08 Apr 2021 00:49:09

Generated On: 10 Jun 2021 09:55:27

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 MAR 2021

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

Comments

*If Contact Not Made, please provide Comments*

US3812085

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 08 Apr 2021 00:49:09

Generated On: 10 Jun 2021 09:55:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3812085

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 03 May 2021 19:24:06

Generated On: 10 Jun 2021 09:55:27

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*

US3812085

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 03 May 2021 19:24:06

Generated On: 10 Jun 2021 09:55:27

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3812085**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:27**

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*



**US3812085**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:27**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3812085

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:55:27

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"/>

US3812085

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 20 Feb 2021 19:39:25

Generated On: 10 Jun 2021 09:55:27

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[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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US3812085

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

Form: Visit Date

Data signed: (b) (4) 20 Feb 2021 19:39:25

Generated On: 10 Jun 2021 09:55:27

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

Visit date (dd MMM yyyy)	27 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3812085

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

Form: Unblinding

Data signed: (b) (4) 26 Mar 2021 19:46:16

Generated On: 10 Jun 2021 09:55:27

Date of updated informed consent (dd MMM yyyy) 27 JAN 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) 27 JAN 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 \_\_\_\_\_

US3812085

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 20 Feb 2021 19:39:25

Generated On: 10 Jun 2021 09:55:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 JAN 2021
Collection time (00:00-23:59)	17:20 (24 HR)
Collection date and time (derived)	27 JAN 2021 17:20

US3812085

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 20 Feb 2021 19:39:25

Generated On: 10 Jun 2021 09:55:27

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 JAN 2021
Collection time (00:00 - 23:59)	17:25
Collection Date and Time (derived)	27 JAN 2021 17:25

US3812085

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 20 Feb 2021 19:39:25

Generated On: 10 Jun 2021 09:55:27

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3812085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

AEID	USA-US111-2021-MRNA-1273-P30 1000009
Adverse event	ALOPECIA AREATA
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)	10 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input 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	

US3812085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

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SUBJECT US3812085 REPORTED AT HIS CLINIC VISIT ON JAN 27, 2021 THAT HE WAS DIAGNOSED WITH ALOPECIA AREATA BY HIS DERMATOLOGIST ON DEC 15, 2020. SUBJECT INITIALLY REPORTED "THINNING BEARD" TO SITE STAFF ON OCTOBER 26, 2020. THE AE STARTED ON SEPTEMBER 10, 2020 AND WAS DETERMINED TO BE RELATED TO IP, AS THE SUBJECT RECEIVED HIS SECOND DOSE OF IP ON SEPTEMBER 02, 2020. THE SUBJECT DENIED HAVING A FAMILY HISTORY OF ALOPECIA AREATA. AS THIS CONDITION IS AN AUTOIMMUNE DISORDER, THE AE WAS CHANGED FROM NOT SERIOUS TO SERIOUS. MEDICAL RECORDS WERE REQUESTED ON JAN 27, 2021.

---

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)	

---

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Mar 2021 19:46:16

Generated On: 10 Jun 2021 09:55:27

---

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

Yes ☒

No ☐

---

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

---

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Mar 2021 19:46:16

Generated On: 10 Jun 2021 09:55:27

Name of Medication TRUVADA

Prophylaxis Yes ☒  
No ☐

Indication HIV PREVENTATIVE

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☒  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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EAB) (1725)

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US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Mar 2021 19:46:16

Generated On: 10 Jun 2021 09:55:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAY 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Mar 2021 19:46:16

Generated On: 10 Jun 2021 09:55:27

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE

Dose per administration 200

Dose unit mg ☒  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

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EAB) (1725)

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US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Mar 2021 19:46:16

Generated On: 10 Jun 2021 09:55:27

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 04 SEP 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Mar 2021 19:46:16

Generated On: 10 Jun 2021 09:55:27

Name of Medication BETAMETHESONE  
DIPROPIONATE 0.5%

Prophylaxis Yes ☐  
No ☒

Indication ALOPECIA AREATA

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☒

If dose unit is Other, specify APPLICATION

Frequency once daily ☐  
twice daily ☒  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☒  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Mar 2021 19:46:16

Generated On: 10 Jun 2021 09:55:27

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 DEC 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)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Mar 2021 19:46:16

Generated On: 10 Jun 2021 09:55:27

Name of Medication EMTRICITABINE 200  
MG/DESCOVY TENEFOVIR  
ALATENAMIDE 25 MG

Prophylaxis Yes ☒  
No ☐

Indication HIV PREVENTATIVE

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☐  
IU ☐  
tablet ☒  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☒  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☐  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Mar 2021 19:46:16

Generated On: 10 Jun 2021 09:55:27

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 OCT 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"/>

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Mar 2021 19:46:16

Generated On: 10 Jun 2021 09:55:27

Name of Medication ACYCLOVIR

Prophylaxis Yes ☐  
No ☒

Indication HERPES SIMPLEX VIRUS TYPE 2

Dose per administration 1

Dose unit mg ☐  
ug ☐  
mL ☐  
g ☒  
IU ☐  
tablet ☐  
capsule ☐  
puff ☐  
Other ☐

If dose unit is Other, specify

Frequency once daily ☐  
twice daily ☐  
three times daily ☐  
four times daily ☐  
every other day ☐  
every week ☐  
every month ☐  
as needed ☒  
once ☐  
unknown ☐  
other ☐

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐  
Intraocular ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Mar 2021 19:46:16

Generated On: 10 Jun 2021 09:55:27

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

US3812085

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 20 Feb 2021 19:39:25

Generated On: 10 Jun 2021 09:55:27

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

US3812085

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:55:27

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



US3812085

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:55:27

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 ☐

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 01 May 2021 20:47:48

Generated On: 10 Jun 2021 09:55:27

SAEID	USA-US111-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	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)	4

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 01 May 2021 20:47:48

Generated On: 10 Jun 2021 09:55:27

SAEID	USA-US111-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	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)	4
Date of submission (Pre-filled from custom function)	29/JAN/2021 14:44
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

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 01 May 2021 20:47:48

Generated On: 10 Jun 2021 09:55:27

SAEID	USA-US111-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	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)	4
Date of submission (Pre-filled from custom function)	26/FEB/2021 09:36
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

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 01 May 2021 20:47:48

Generated On: 10 Jun 2021 09:55:27

SAEID	USA-US111-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	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)	4
Date of submission (Pre-filled from custom function)	18/MAR/2021 13:22
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

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 01 May 2021 20:47:48

Generated On: 10 Jun 2021 09:55:27

SAEID	USA-US111-2021-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	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)	4
Date of submission (Pre-filled from custom function)	30/APR/2021 10:56
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

US3812085 (Prod: Sundance Clinical Research - Platinum - PPDS)

**US3812085**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:55:27**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'US3812085'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:55:29



US3812085

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:55:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Heather Cherniawski	08 Aug 2020 15:17:15

US3812085

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '08 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:55:30

**US3812085**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:55:27**

[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 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Clinic (Clinic)'	Heather Cherniawski (b) (4)	08 Aug 2020 15:17:15

**US3812085**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:55:27**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered 'SCRN'	System	08 Aug 2020 15:17:15

US3812085

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:55:27

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered (b) (6) 1989'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:55:31

**US3812085**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:27**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '31'	Heather Cherniawski (b) (4)	08 Aug 2020 15:17:47

**US3812085**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:27**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered 'YEARS'	System	08 Aug 2020 15:17:47

**US3812085**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:27**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered '31'	System	08 Aug 2020 15:18:10



**US3812085**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:27**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Male (M)'	Heather Cherniawski (b) (4)	08 Aug 2020 15:17:47

US3812085

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:55:27

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Heather Cherniawski (b) (4)	08 Aug 2020 15:17:47

**US3812085**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:27**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '0'	Heather Cherniawski (b) (4)	08 Aug 2020 15:17:47

**US3812085**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:27**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '0'	Heather Cherniawski (b) (4)	08 Aug 2020 15:17:47

**US3812085**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:27**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'I'	Heather Cherniawski (b) (4)	08 Aug 2020 15:17:47

US3812085

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:55:27

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '0'	Heather Cherniawski (b) (4)	08 Aug 2020 15:17:47

**US3812085**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:27**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '0'	Heather Cherniawski	08 Aug 2020 15:17:47

**US3812085**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:27**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '0'	Heather Cherniawski (b) (4)	08 Aug 2020 15:17:47



US3812085

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:55:27

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Heather Cherniawski (b) (4)	08 Aug 2020 15:17:47

**US3812085**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:27**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '0'	Heather Cherniawski (b) (4)	08 Aug 2020 15:17:47

**US3812085**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:55:27**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '0'	Heather Cherniawski (b) (4)	08 Aug 2020 15:17:47

US3812085

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:55:27

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '08 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 00:15:34
User entered '8 Aug 2020'	(b) (4)	
	Heather Cherniawski	08 Aug 2020 15:18:10
	(b) (4)	

**US3812085**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:55:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered 'Aug 2020'	System	08 Aug 2020 15:18:10

**US3812085**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:55:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered '2020'	System	08 Aug 2020 15:18:10

US3812085

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:55:27

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	08 Aug 2020 15:18:17
User entered 'Amendment 1 (1)' reason for change: Data Entry Error	Heather Cherniawski	08 Aug 2020 15:18:17
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	08 Aug 2020 15:18:10
	Heather Cherniawski	08 Aug 2020 15:18:10
	(b) (4)	

US3812085

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:55:27

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	08 Aug 2020 15:18:10



**US3812085**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:55:27**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Heather Cherniawski (b) (4)	08 Aug 2020 15:18:10

US3812085

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:55:27

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Heather Cherniawski (b) (4)	08 Aug 2020 15:18:10

US3812085

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:55:27

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'No (N)'	Heather Cherniawski	08 Aug 2020 15:18:10

US3812085

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:55:27

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:55:30

**US3812085**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:55:27**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered 'I'	System	08 Aug 2020 15:18:22

US3812085

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:55:27

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Heather Cherniawski	08 Aug 2020 15:18:22

**US3812085**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:55:27**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 18:21:34

US3812085

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:55:27

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex type II - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 16:37:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Mar 2021 16:37:36
Data point term sent to Coder	System	24 Mar 2021 16:36:42
Coding entries removed.	Breanna Galibert (b) (4)	24 Mar 2021 16:36:40
Signature has been broken.	Breanna Galibert (b) (4)	24 Mar 2021 16:36:40
User entered 'Herpes simplex virus TYPE 2' reason for change: Data Entry Error	Breanna Galibert (b) (4)	24 Mar 2021 16:36:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Herpes simplex, LLT: Herpes simplex type II - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 08:17:23
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 08:17:23
Data point term sent to Coder	System	10 Aug 2020 18:22:24
User entered 'HSV2'	Breanna Galibert (b) (4)	10 Aug 2020 18:21:48



**US3812085**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:55:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'UN Feb 2020'	Breanna Galibert (b) (4)	10 Aug 2020 18:21:48

US3812085

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:55:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '0'	Breanna Galibert (b) (4)	10 Aug 2020 18:21:48

**US3812085**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 18:21:48

**US3812085**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:55:27**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 18:21:48

**US3812085**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '0'	Breanna Galibert (b) (4)	10 Aug 2020 18:21:48

**US3812085**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered 'Feb 2020'	System	10 Aug 2020 18:21:48

**US3812085**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered '2020'	System	10 Aug 2020 18:21:48

**US3812085**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered empty.	System	10 Aug 2020 18:21:48



**US3812085**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered empty.	System	10 Aug 2020 18:21:48

US3812085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 18:22:27

US3812085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '08 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 00:15:40
User entered '8 Aug 2020'	(b) (4)	
	Breanna Galibert (b) (4)	10 Aug 2020 18:22:27
	(b) (4)	

US3812085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '09:21'	Breanna Galibert (b) (4)	10 Aug 2020 18:22:27

**US3812085**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:27**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered '08 Aug 2020 09:21'	System	11 Nov 2020 00:15:40
User entered '8 Aug 2020 09:21'	System	10 Aug 2020 18:22:27

US3812085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '74.0' in	Breanna Galibert (b) (4)	10 Aug 2020 18:22:27
DataPoint set to visible.	System	08 Aug 2020 15:18:22

US3812085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '157.2' lb	Breanna Galibert (b) (4)	10 Aug 2020 18:22:27
DataPoint set to visible.	System	08 Aug 2020 15:18:22

US3812085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
Amendment Manager: User entered '20.22549'	System	16 Sep 2020 23:48:40
User entered '20.2'	System	10 Aug 2020 18:22:27
DataPoint set to visible.	System	08 Aug 2020 15:18:22



**US3812085**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:27**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered 'kg/m2'	System	10 Aug 2020 18:22:27
DataPoint set to visible.	System	08 Aug 2020 15:18:22

US3812085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 18:22:27

US3812085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Other (Other)'	Breanna Galibert (b) (4)	10 Aug 2020 18:22:27

US3812085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 18:22:27

**US3812085**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:27**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 18:22:27

**US3812085**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:27**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered 'bpm'	System	10 Aug 2020 18:22:27

US3812085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 18:22:27

US3812085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered 'breaths/min'	System	10 Aug 2020 18:22:27



US3812085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 18:22:27

**US3812085**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:27**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered 'mmHg'	System	10 Aug 2020 18:22:27

US3812085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 18:22:27

**US3812085**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:27**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered 'mmHg'	System	10 Aug 2020 18:22:27

US3812085

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 09:01:46

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46

US3812085

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:55:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 18:22:38

US3812085

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:55:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '08 Aug 2020' reason for change: Data Entry Error	(b) (4)	
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	Maureen Dempsey (b) (4)	11 Nov 2020 00:15:47
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	07 Sep 2020 10:59:13
User entered '8 Aug 2020'	Breanna Galibert (b) (4)	02 Sep 2020 23:21:12
	(b) (4)	10 Aug 2020 18:22:38



US3812085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:27

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:11

US3812085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:27

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:11

US3812085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:27

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:11

US3812085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:27

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:11

US3812085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:27

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:11

US3812085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:27

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:11

US3812085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:27

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:11

US3812085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:27

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:11



US3812085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:27

**Hospitality and Tourism Workers** (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	24 Aug 2020 23:16:06
User entered 'No (N)' reason for change: Data Entry Error	System	24 Aug 2020 23:16:06
User opened query 'Data is required. Please complete.' (Site from System).	Anya Penly (b) (4)	24 Aug 2020 23:16:06
User entered empty.	(b) (4)	
	System	10 Aug 2020 18:23:11
	Breanna Galibert (b) (4)	10 Aug 2020 18:23:11
	(b) (4)	

US3812085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:27

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:11

US3812085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:27

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:11

**US3812085**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:55:27**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:11

US3812085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 18:23:11

US3812085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:27

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'I'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:11

US3812085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:27

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '0'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:11

US3812085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:27

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '0'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:11



US3812085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:27

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '0'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:11

US3812085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:27

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '0'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:11

US3812085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:27

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '0'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:11

US3812085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:27

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '0'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:11

US3812085

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:55:27

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 18:23:11

US3812085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:55:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Heather Cherniawski (b) (4)	08 Aug 2020 15:18:36

US3812085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:55:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '08 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 00:15:57
User entered '8 Aug 2020'	(b) (4)	
	Heather Cherniawski	08 Aug 2020 15:18:36
	(b) (4)	

US3812085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:55:27

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Clinic (Clinic)'	Heather Cherniawski	08 Aug 2020 15:18:36



US3812085

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:55:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'VISIT1'	System	08 Aug 2020 15:18:36

US3812085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '08 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:55:32

US3812085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:55:27

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 03:05:02
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 03:05:02
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	08 Aug 2020 14:55:32
User entered '102255' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:55:32

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:55:27

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	08 Aug 2020 14:55:32

US3812085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:55:27

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:30

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:55:27

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:30

US3812085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:55:27

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:30

US3812085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:55:27

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:30



US3812085

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:55:27

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 18:23:30

US3812085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:55:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52

US3812085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:55:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52

US3812085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:55:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52

US3812085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:55:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52

US3812085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4) (b) (4)	10 Aug 2020 18:24:52

US3812085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '08 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 00:16:14
User entered '8 Aug 2020'	(b) (4)	
	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52
	(b) (4)	



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '09:21'	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered '08 Aug 2020 09:21'	System	11 Nov 2020 00:16:14
User entered '8 Aug 2020 09:21'	System	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '97.7' F	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52

US3812085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52

US3812085

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '64'	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'bpm'	System	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '16'	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'breaths/min'	System	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '96'	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'mmHg'	System	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '76'	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'mmHg'	System	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:55:27

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:55:27

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered missing code ND - Not Done.	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4) (b) (4)	10 Aug 2020 18:24:52



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '08 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 00:16:14
User entered '8 Aug 2020'	(b) (4)	
	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
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 13:32:43
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 18:24:52
User entered '10:39'	Breanna Galibert (b) (4) (b) (4)	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered '08 Aug 2020 10:39'	System	11 Nov 2020 00:16:14
User entered '8 Aug 2020 10:39'	System	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '97.9' F	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '60'	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'bpm'	System	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '16'	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'breaths/min'	System	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '100'	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'mmHg'	System	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '72'	Breanna Galibert (b) (4)	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'mmHg'	System	10 Aug 2020 18:24:52

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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:55:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 18:24:59



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Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:55:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 18:24:59

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:55:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Heather Cherniawski	08 Aug 2020 15:20:03

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:55:27

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Heather Cherniawski	08 Aug 2020 15:20:03

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Heather Cherniawski (b) (4)	08 Aug 2020 15:20:03

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:55:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'MRNA-1273 OR PLACEBO'	System	08 Aug 2020 15:20:03

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:55:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '08 Aug 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	11 Nov 2020 00:16:28
User entered '8 Aug 2020'	Heather Cherniawski	08 Aug 2020 15:20:03

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:55:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '10:07'	Heather Cherniawski	08 Aug 2020 15:20:03

US3812085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:55:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered '08 Aug 2020 10:07'	System	11 Nov 2020 00:16:28
User entered '8 Aug 2020 10:07'	System	08 Aug 2020 15:20:03



US3812085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:55:27

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Left Arm (LEFT ARM)'	Heather Cherniawski	08 Aug 2020 15:20:03

US3812085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:55:27

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'ONCE'	System	08 Aug 2020 15:20:03

US3812085

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:55:27

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'INTRAMUSCULAR'	System	08 Aug 2020 15:20:03

US3812085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 18:25:17

US3812085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '08 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 00:16:36
User entered '8 Aug 2020'	(b) (4)	
	Breanna Galibert (b) (4)	10 Aug 2020 18:25:17
	(b) (4)	

US3812085

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '10:00'	Breanna Galibert (b) (4)	10 Aug 2020 18:25:17

**US3812085**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:55:27**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered '08 Aug 2020 10:00'	System	11 Nov 2020 00:16:36
User entered '8 Aug 2020 10:00'	System	10 Aug 2020 18:25:17

US3812085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:55:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '08 Aug 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 00:16:43
User entered '8 Aug 2020'	(b) (4)	
	Breanna Galibert (b) (4)	10 Aug 2020 18:25:29
	(b) (4)	



US3812085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:55:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Breanna Galibert (b) (4) (b) (4)	10 Aug 2020 18:25:29

US3812085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:55:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 18:25:29

US3812085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:55:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '10:02'	Breanna Galibert (b) (4)	10 Aug 2020 18:25:29

**US3812085**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered '08 Aug 2020 10:02'	System	11 Nov 2020 00:16:43
User entered '8 Aug 2020 10:02'	System	10 Aug 2020 18:25:29

US3812085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:55:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Breanna Galibert (b) (4) (b) (4)	10 Aug 2020 18:25:29

US3812085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:55:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 18:25:29

US3812085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:55:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 18:25:29

US3812085

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:55:27

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered empty.	System	10 Aug 2020 18:25:29



US3812085

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:55:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	15 Aug 2020 18:22:06

**US3812085**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'I'	System	15 Aug 2020 18:22:06

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T10:43:43', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ffa147bf-ef49-42b4-93f6-49f023677d47'	System	08 Aug 2020 15:44:09
User entered 'Yes (Y)'	System	08 Aug 2020 15:44:09

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T10:43:49', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ffa147bf-ef49-42b4-93f6-49f023677d47'	System	08 Aug 2020 15:44:09
User entered '97.9'	System	08 Aug 2020 15:44:09

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T10:43:55', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ffa147bf-ef49-42b4-93f6-49f023677d47'	System	08 Aug 2020 15:44:09
User entered 'No (N)'	System	08 Aug 2020 15:44:09

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T10:44:06', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ffa147bf-ef49-42b4-93f6-49f023677d47'	System	08 Aug 2020 15:44:09
User entered '08 Aug 2020 10:44'	System	08 Aug 2020 15:44:09

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '08 Aug 2020 10:27'	System	08 Aug 2020 15:20:03



US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '08 Aug 2020 12:57'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T14:05:58', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '3f033417-58ea-4b38-8cb8-54d9d1907086'	System	08 Aug 2020 19:06:20
User entered 'Yes (Y)'	System	08 Aug 2020 19:06:20

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T14:06:07', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '3f033417-58ea-4b38-8cb8-54d9d1907086' User entered '97.9'	System	08 Aug 2020 19:06:20
	System	08 Aug 2020 19:06:20

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T14:06:11', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '3f033417-58ea-4b38-8cb8-54d9d1907086'	System	08 Aug 2020 19:06:20
User entered 'No (N)'	System	08 Aug 2020 19:06:20

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T14:06:15', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '3f033417-58ea-4b38-8cb8-54d9d1907086'	System	08 Aug 2020 19:06:20
User entered '08 Aug 2020 14:06'	System	08 Aug 2020 19:06:20

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '08 Aug 2020 13:52'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 15:20:03



US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 2'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-09T12:00:26', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '832c8450-f8e3-43dd-8161-09f9a7eb363a'	System	09 Aug 2020 17:00:41
User entered 'Yes (Y)'	System	09 Aug 2020 17:00:41

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-09T12:00:31', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '832c8450-f8e3-43dd-8161-09f9a7eb363a'	System	09 Aug 2020 17:00:41
User entered '98.0'	System	09 Aug 2020 17:00:41

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-09T12:00:34', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '832c8450-f8e3-43dd-8161-09f9a7eb363a'	System	09 Aug 2020 17:00:41
User entered 'No (N)'	System	09 Aug 2020 17:00:41

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-09T12:00:38', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '832c8450-f8e3-43dd-8161-09f9a7eb363a'	System	09 Aug 2020 17:00:41
User entered '09 Aug 2020 12:00'	System	09 Aug 2020 17:00:41

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 3'	System	08 Aug 2020 15:20:03



US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-10T12:00:45', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a406a193-8f10-426d-9fe5-5fc67a07fab5'	System	10 Aug 2020 17:00:57
User entered 'Yes (Y)'	System	10 Aug 2020 17:00:57

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-10T12:00:49', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a406a193-8f10-426d-9fe5-5fc67a07fab5' User entered '98.1'	System	10 Aug 2020 17:00:57
	System	10 Aug 2020 17:00:57

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-10T12:00:51', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a406a193-8f10-426d-9fe5-5fc67a07fab5'	System	10 Aug 2020 17:00:57
User entered 'No (N)'	System	10 Aug 2020 17:00:57

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-10T12:00:54', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a406a193-8f10-426d-9fe5-5fc67a07fab5'	System	10 Aug 2020 17:00:57
User entered '10 Aug 2020 12:00'	System	10 Aug 2020 17:00:57

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 4'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-11T12:00:34', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1a66666c-6cb8-40c1-9763-5cad51124f81'	System	11 Aug 2020 17:00:49
User entered 'Yes (Y)'	System	11 Aug 2020 17:00:49



US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-11T12:00:40', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1a66666c-6cb8-40c1-9763-5cad51124f81'	System	11 Aug 2020 17:00:49
User entered '97.9'	System	11 Aug 2020 17:00:49

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-11T12:00:42', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1a66666c-6cb8-40c1-9763-5cad51124f81'	System	11 Aug 2020 17:00:49
User entered 'No (N)'	System	11 Aug 2020 17:00:49

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-11T12:00:46', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1a66666c-6cb8-40c1-9763-5cad51124f81'	System	11 Aug 2020 17:00:49
User entered '11 Aug 2020 12:00'	System	11 Aug 2020 17:00:49

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 5'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-12T12:00:32', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'c28519a5-ea16-4fc7-82f3-744c7ad95313'	System	12 Aug 2020 17:00:52
User entered 'Yes (Y)'	System	12 Aug 2020 17:00:52

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-12T12:00:36', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'c28519a5-ea16-4fc7-82f3-744c7ad95313'	System	12 Aug 2020 17:00:52
User entered '98.0'	System	12 Aug 2020 17:00:52



US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-12T12:00:39', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'c28519a5-ea16-4fc7-82f3-744c7ad95313'	System	12 Aug 2020 17:00:52
User entered 'No (N)'	System	12 Aug 2020 17:00:52

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-12T12:00:43', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'c28519a5-ea16-4fc7-82f3-744c7ad95313'	System	12 Aug 2020 17:00:52
User entered '12 Aug 2020 12:00'	System	12 Aug 2020 17:00:52

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 6'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-13T12:03:59', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '437d42d2-3733-4436-b129-4a66836a01ec'	System	13 Aug 2020 17:04:19
User entered 'Yes (Y)'	System	13 Aug 2020 17:04:19

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-13T12:04:04', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '437d42d2-3733-4436-b129-4a66836a01ec'	System	13 Aug 2020 17:04:19
User entered '98.0'	System	13 Aug 2020 17:04:19

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-13T12:04:10', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '437d42d2-3733-4436-b129-4a66836a01ec'	System	13 Aug 2020 17:04:19
User entered 'No (N)'	System	13 Aug 2020 17:04:19



US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-13T12:04:14', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '437d42d2-3733-4436-b129-4a66836a01ec'	System	13 Aug 2020 17:04:19
User entered '13 Aug 2020 12:04'	System	13 Aug 2020 17:04:19

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 7'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-14T12:00:17', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'fca80c75-6d81-4fba-ab94-48291d3c80bd'	System	14 Aug 2020 17:00:37
User entered 'Yes (Y)'	System	14 Aug 2020 17:00:37

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-14T12:00:20', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'fca80c75-6d81-4fba-ab94-48291d3c80bd'	System	14 Aug 2020 17:00:37
User entered '98.1'	System	14 Aug 2020 17:00:37

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-14T12:00:24', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'fca80c75-6d81-4fba-ab94-48291d3c80bd'	System	14 Aug 2020 17:00:37
User entered 'No (N)'	System	14 Aug 2020 17:00:37

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-14T12:00:29', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'fca80c75-6d81-4fba-ab94-48291d3c80bd'	System	14 Aug 2020 17:00:37
User entered '14 Aug 2020 12:00'	System	14 Aug 2020 17:00:37



US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T10:44:31', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ec8f8795-9eab-4b14-b160-d9160e0cc7dd'	System	08 Aug 2020 15:44:58
User entered 'None (1)'	System	08 Aug 2020 15:44:58

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T10:44:36', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ec8f8795-9eab-4b14-b160-d9160e0cc7dd'	System	08 Aug 2020 15:44:58
User entered 'No (N)'	System	08 Aug 2020 15:44:58

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T10:44:40', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ec8f8795-9eab-4b14-b160-d9160e0cc7dd'	System	08 Aug 2020 15:44:58
User entered 'No (N)'	System	08 Aug 2020 15:44:58

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T10:44:50', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ec8f8795-9eab-4b14-b160-d9160e0cc7dd'	System	08 Aug 2020 15:44:58
User entered 'None (1)'	System	08 Aug 2020 15:44:58

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T10:44:56', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ec8f8795-9eab-4b14-b160-d9160e0cc7dd'	System	08 Aug 2020 15:44:58
User entered '08 Aug 2020 10:44'	System	08 Aug 2020 15:44:58



US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '08 Aug 2020 10:27'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '08 Aug 2020 12:57'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T14:06:22', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '0315a41f-3a69-4f19-b930-9bea6f8697d3'	System	08 Aug 2020 19:06:42
User entered 'None (1)'	System	08 Aug 2020 19:06:42

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T14:06:26', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '0315a41f-3a69-4f19-b930-9bea6f8697d3'	System	08 Aug 2020 19:06:42
User entered 'No (N)'	System	08 Aug 2020 19:06:42

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T14:06:30', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '0315a41f-3a69-4f19-b930-9bea6f8697d3'	System	08 Aug 2020 19:06:42
User entered 'No (N)'	System	08 Aug 2020 19:06:42

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T14:06:36', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '0315a41f-3a69-4f19-b930-9bea6f8697d3'	System	08 Aug 2020 19:06:42
User entered 'None (1)'	System	08 Aug 2020 19:06:42

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T14:06:39', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '0315a41f-3a69-4f19-b930-9bea6f8697d3'	System	08 Aug 2020 19:06:42
User entered '08 Aug 2020 14:06'	System	08 Aug 2020 19:06:42



US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '08 Aug 2020 13:52'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 2'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-09T12:00:53', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '5e875b8d-4297-4610-84a7-0a11e71debe1'	System	09 Aug 2020 17:01:13
User entered 'Does not interfere with activity (2)'	System	09 Aug 2020 17:01:13

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-09T12:00:56', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '5e875b8d-4297-4610-84a7-0a11e71debe1'	System	09 Aug 2020 17:01:13
User entered 'No (N)'	System	09 Aug 2020 17:01:13

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-09T12:01:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '5e875b8d-4297-4610-84a7-0a11e71debe1'	System	09 Aug 2020 17:01:13
User entered 'No (N)'	System	09 Aug 2020 17:01:13

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-09T12:01:05', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '5e875b8d-4297-4610-84a7-0a11e71debe1'	System	09 Aug 2020 17:01:13
User entered 'None (1)'	System	09 Aug 2020 17:01:13

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-09T12:01:11', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '5e875b8d-4297-4610-84a7-0a11e71debe1' User entered '09 Aug 2020 12:01'	System	09 Aug 2020 17:01:13
	System	09 Aug 2020 17:01:13



US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 3'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-10T12:01:02', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a042b93b-acfc-428c-839f-ca93c3ad7e06'	System	10 Aug 2020 17:01:23
User entered 'None (1)'	System	10 Aug 2020 17:01:23

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-10T12:01:05', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a042b93b-acfc-428c-839f-ca93c3ad7e06'	System	10 Aug 2020 17:01:23
User entered 'No (N)'	System	10 Aug 2020 17:01:23

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-10T12:01:09', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a042b93b-acfc-428c-839f-ca93c3ad7e06'	System	10 Aug 2020 17:01:23
User entered 'No (N)'	System	10 Aug 2020 17:01:23

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-10T12:01:13', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a042b93b-acfc-428c-839f-ca93c3ad7e06'	System	10 Aug 2020 17:01:23
User entered 'None (1)'	System	10 Aug 2020 17:01:23

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-10T12:01:20', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a042b93b-acfc-428c-839f-ca93c3ad7e06'	System	10 Aug 2020 17:01:23
User entered '10 Aug 2020 12:01'	System	10 Aug 2020 17:01:23



US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 4'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-11T12:00:51', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '41aaf34c-7804-44e0-bb54-38b8d1186262'	System	11 Aug 2020 17:01:09
User entered 'None (1)'	System	11 Aug 2020 17:01:09

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-11T12:00:54', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '41aaf34c-7804-44e0-bb54-38b8d1186262'	System	11 Aug 2020 17:01:09
User entered 'No (N)'	System	11 Aug 2020 17:01:09

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-11T12:00:56', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '41aaf34c-7804-44e0-bb54-38b8d1186262'	System	11 Aug 2020 17:01:09
User entered 'No (N)'	System	11 Aug 2020 17:01:09

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-11T12:00:59', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '41aaf34c-7804-44e0-bb54-38b8d1186262'	System	11 Aug 2020 17:01:09
User entered 'None (1)'	System	11 Aug 2020 17:01:09

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-11T12:01:03', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '41aaf34c-7804-44e0-bb54-38b8d1186262'	System	11 Aug 2020 17:01:09
User entered '11 Aug 2020 12:01'	System	11 Aug 2020 17:01:09



US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 5'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-12T12:00:47', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '539be065-677c-4d9b-8daa-a1eed89c7eee'	System	12 Aug 2020 17:01:12
User entered 'None (1)'	System	12 Aug 2020 17:01:12

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-12T12:00:49', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '539be065-677c-4d9b-8daa-a1eed89c7eee'	System	12 Aug 2020 17:01:12
User entered 'No (N)'	System	12 Aug 2020 17:01:12

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-12T12:00:52', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '539be065-677c-4d9b-8daa-a1eed89c7eee'	System	12 Aug 2020 17:01:12
User entered 'No (N)'	System	12 Aug 2020 17:01:12

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-12T12:00:54', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '539be065-677c-4d9b-8daa-a1eed89c7eee'	System	12 Aug 2020 17:01:12
User entered 'None (1)'	System	12 Aug 2020 17:01:12

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-12T12:00:58', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '539be065-677c-4d9b-8daa-a1eed89c7eee'	System	12 Aug 2020 17:01:12
User entered '12 Aug 2020 12:00'	System	12 Aug 2020 17:01:12



US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 6'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-13T12:04:23', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1486a668-563b-4093-baef-5e912fe9647e'	System	13 Aug 2020 17:04:36
User entered 'None (1)'	System	13 Aug 2020 17:04:36

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-13T12:04:26', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1486a668-563b-4093-baef-5e912fe9647e'	System	13 Aug 2020 17:04:36
User entered 'No (N)'	System	13 Aug 2020 17:04:36

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-13T12:04:28', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1486a668-563b-4093-baef-5e912fe9647e'	System	13 Aug 2020 17:04:36
User entered 'No (N)'	System	13 Aug 2020 17:04:36

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-13T12:04:30', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1486a668-563b-4093-baef-5e912fe9647e'	System	13 Aug 2020 17:04:36
User entered 'None (1)'	System	13 Aug 2020 17:04:36

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-13T12:04:34', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1486a668-563b-4093-baef-5e912fe9647e'	System	13 Aug 2020 17:04:36
User entered '13 Aug 2020 12:04'	System	13 Aug 2020 17:04:36



US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 7'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-14T12:00:34', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'abcf2170-3e86-44e8-8e20-57ecd1a794d4'	System	14 Aug 2020 17:00:54
User entered 'None (1)'	System	14 Aug 2020 17:00:54

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-14T12:00:38', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'abcf2170-3e86-44e8-8e20-57ecd1a794d4'	System	14 Aug 2020 17:00:54
User entered 'No (N)'	System	14 Aug 2020 17:00:54

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-14T12:00:39', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'abcf2170-3e86-44e8-8e20-57ecd1a794d4'	System	14 Aug 2020 17:00:54
User entered 'No (N)'	System	14 Aug 2020 17:00:54

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-14T12:00:42', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'abcf2170-3e86-44e8-8e20-57ecd1a794d4'	System	14 Aug 2020 17:00:54
User entered 'None (1)'	System	14 Aug 2020 17:00:54

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-14T12:00:45', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'abcf2170-3e86-44e8-8e20-57ecd1a794d4'	System	14 Aug 2020 17:00:54
User entered '14 Aug 2020 12:00'	System	14 Aug 2020 17:00:54



US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T10:45:10', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '6bc9f545-7f8a-4d68-a8be-204fc7a6fa91'	System	08 Aug 2020 15:45:40
User entered 'None (0)'	System	08 Aug 2020 15:45:40

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T10:45:12', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '6bc9f545-7f8a-4d68-a8be-204fc7a6fa91'	System	08 Aug 2020 15:45:40
User entered 'None (0)'	System	08 Aug 2020 15:45:40

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T10:45:18', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '6bc9f545-7f8a-4d68-a8be-204fc7a6fa91'	System	08 Aug 2020 15:45:40
User entered 'None (0)'	System	08 Aug 2020 15:45:40

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T10:45:22', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '6bc9f545-7f8a-4d68-a8be-204fc7a6fa91'	System	08 Aug 2020 15:45:40
User entered 'None (0)'	System	08 Aug 2020 15:45:40

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T10:45:26', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '6bc9f545-7f8a-4d68-a8be-204fc7a6fa91'	System	08 Aug 2020 15:45:40
User entered 'None (0)'	System	08 Aug 2020 15:45:40



US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T10:45:28', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '6bc9f545-7f8a-4d68-a8be-204fc7a6fa91'	System	08 Aug 2020 15:45:40
User entered 'None (0)'	System	08 Aug 2020 15:45:40

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T10:45:32', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '6bc9f545-7f8a-4d68-a8be-204fc7a6fa91'	System	08 Aug 2020 15:45:40
User entered 'No (N)'	System	08 Aug 2020 15:45:40

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T10:45:36', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '6bc9f545-7f8a-4d68-a8be-204fc7a6fa91'	System	08 Aug 2020 15:45:40
User entered '08 Aug 2020 10:45'	System	08 Aug 2020 15:45:40

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '08 Aug 2020 10:27'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '08 Aug 2020 12:57'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 1, after vaccination (at home)'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T14:06:51', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a1ca82f9-4248-4951-ae30-d0cf696d645c'	System	08 Aug 2020 19:07:30
User entered 'None (0)'	System	08 Aug 2020 19:07:30

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T14:06:54', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a1ca82f9-4248-4951-ae30-d0cf696d645c'	System	08 Aug 2020 19:07:30
User entered 'None (0)'	System	08 Aug 2020 19:07:30



US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T14:06:58', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a1ca82f9-4248-4951-ae30-d0cf696d645c'	System	08 Aug 2020 19:07:30
User entered 'None (0)'	System	08 Aug 2020 19:07:30

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T14:07:01', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a1ca82f9-4248-4951-ae30-d0cf696d645c'	System	08 Aug 2020 19:07:30
User entered 'None (0)'	System	08 Aug 2020 19:07:30

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T14:07:07', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a1ca82f9-4248-4951-ae30-d0cf696d645c'	System	08 Aug 2020 19:07:30
User entered 'None (0)'	System	08 Aug 2020 19:07:30

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T14:07:10', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a1ca82f9-4248-4951-ae30-d0cf696d645c'	System	08 Aug 2020 19:07:30
User entered 'None (0)'	System	08 Aug 2020 19:07:30

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T14:07:15', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a1ca82f9-4248-4951-ae30-d0cf696d645c'	System	08 Aug 2020 19:07:30
User entered 'No (N)'	System	08 Aug 2020 19:07:30

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-08T14:07:26', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a1ca82f9-4248-4951-ae30-d0cf696d645c'	System	08 Aug 2020 19:07:30
User entered '08 Aug 2020 14:07'	System	08 Aug 2020 19:07:30

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '08 Aug 2020 13:52'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '09 Aug 2020 11:59'	System	08 Aug 2020 15:20:03



US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 2'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-09T12:01:18', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '545b5851-e3c7-492e-b8d8-fb65716cf5f7'	System	09 Aug 2020 17:01:48
User entered 'None (0)'	System	09 Aug 2020 17:01:48

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-09T12:01:25', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '545b5851-e3c7-492e-b8d8-fb65716cf5f7'	System	09 Aug 2020 17:01:48
User entered 'None (0)'	System	09 Aug 2020 17:01:48

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-09T12:01:30', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '545b5851-e3c7-492e-b8d8-fb65716cf5f7'	System	09 Aug 2020 17:01:48
User entered 'None (0)'	System	09 Aug 2020 17:01:48

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-09T12:01:33', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '545b5851-e3c7-492e-b8d8-fb65716cf5f7'	System	09 Aug 2020 17:01:48
User entered 'None (0)'	System	09 Aug 2020 17:01:48

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-09T12:01:35', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '545b5851-e3c7-492e-b8d8-fb65716cf5f7'	System	09 Aug 2020 17:01:48
User entered 'None (0)'	System	09 Aug 2020 17:01:48

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-09T12:01:37', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '545b5851-e3c7-492e-b8d8-fb65716cf5f7'	System	09 Aug 2020 17:01:48
User entered 'None (0)'	System	09 Aug 2020 17:01:48

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-09T12:01:40', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '545b5851-e3c7-492e-b8d8-fb65716cf5f7'	System	09 Aug 2020 17:01:48
User entered 'No (N)'	System	09 Aug 2020 17:01:48



US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-09T12:01:46', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '545b5851-e3c7-492e-b8d8-fb65716cf5f7'	System	09 Aug 2020 17:01:48
User entered '09 Aug 2020 12:01'	System	09 Aug 2020 17:01:48

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '09 Aug 2020 12:00'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '10 Aug 2020 11:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 3'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-10T12:02:18', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '98c3bf62-289f-461f-afd6-98170bc7eb25'	System	10 Aug 2020 17:02:41
User entered 'None (0)'	System	10 Aug 2020 17:02:41

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-10T12:02:22', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '98c3bf62-289f-461f-afd6-98170bc7eb25'	System	10 Aug 2020 17:02:41
User entered 'None (0)'	System	10 Aug 2020 17:02:41

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-10T12:02:23', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '98c3bf62-289f-461f-afd6-98170bc7eb25'	System	10 Aug 2020 17:02:41
User entered 'None (0)'	System	10 Aug 2020 17:02:41

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-10T12:02:25', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '98c3bf62-289f-461f-afd6-98170bc7eb25'	System	10 Aug 2020 17:02:41
User entered 'None (0)'	System	10 Aug 2020 17:02:41



US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-10T12:02:28', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '98c3bf62-289f-461f-afd6-98170bc7eb25'	System	10 Aug 2020 17:02:41
User entered 'None (0)'	System	10 Aug 2020 17:02:41

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-10T12:02:29', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '98c3bf62-289f-461f-afd6-98170bc7eb25'	System	10 Aug 2020 17:02:41
User entered 'None (0)'	System	10 Aug 2020 17:02:41

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-10T12:02:34', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '98c3bf62-289f-461f-afd6-98170bc7eb25'	System	10 Aug 2020 17:02:41
User entered 'No (N)'	System	10 Aug 2020 17:02:41

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-10T12:02:38', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '98c3bf62-289f-461f-afd6-98170bc7eb25'	System	10 Aug 2020 17:02:41
User entered '10 Aug 2020 12:02'	System	10 Aug 2020 17:02:41

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '10 Aug 2020 12:00'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '11 Aug 2020 11:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 4'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-11T12:01:07', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '4cf2f397-c26b-449a-b5ed-b02c3b035104'	System	11 Aug 2020 17:01:21
User entered 'None (0)'	System	11 Aug 2020 17:01:21



US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-11T12:01:08', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '4cf2f397-c26b-449a-b5ed-b02c3b035104'	System	11 Aug 2020 17:01:21
User entered 'None (0)'	System	11 Aug 2020 17:01:21

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-11T12:01:09', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '4cf2f397-c26b-449a-b5ed-b02c3b035104'	System	11 Aug 2020 17:01:21
User entered 'None (0)'	System	11 Aug 2020 17:01:21

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-11T12:01:10', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '4cf2f397-c26b-449a-b5ed-b02c3b035104'	System	11 Aug 2020 17:01:21
User entered 'None (0)'	System	11 Aug 2020 17:01:21

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-11T12:01:12', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '4cf2f397-c26b-449a-b5ed-b02c3b035104'	System	11 Aug 2020 17:01:21
User entered 'None (0)'	System	11 Aug 2020 17:01:21

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-11T12:01:13', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '4cf2f397-c26b-449a-b5ed-b02c3b035104'	System	11 Aug 2020 17:01:21
User entered 'None (0)'	System	11 Aug 2020 17:01:21

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-11T12:01:17', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '4cf2f397-c26b-449a-b5ed-b02c3b035104'	System	11 Aug 2020 17:01:21
User entered 'No (N)'	System	11 Aug 2020 17:01:21

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-11T12:01:19', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '4cf2f397-c26b-449a-b5ed-b02c3b035104'	System	11 Aug 2020 17:01:21
User entered '11 Aug 2020 12:01'	System	11 Aug 2020 17:01:21

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '11 Aug 2020 12:00'	System	08 Aug 2020 15:20:03



US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '12 Aug 2020 11:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 5'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-12T12:01:01', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '200bca8c-f1e1-44e6-a068-11f41d0342b4'	System	12 Aug 2020 17:01:29
User entered 'None (0)'	System	12 Aug 2020 17:01:29

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-12T12:01:03', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '200bca8c-f1e1-44e6-a068-11f41d0342b4'	System	12 Aug 2020 17:01:29
User entered 'None (0)'	System	12 Aug 2020 17:01:29

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-12T12:01:04', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '200bca8c-f1e1-44e6-a068-11f41d0342b4'	System	12 Aug 2020 17:01:29
User entered 'None (0)'	System	12 Aug 2020 17:01:29

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-12T12:01:06', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '200bca8c-f1e1-44e6-a068-11f41d0342b4'	System	12 Aug 2020 17:01:29
User entered 'None (0)'	System	12 Aug 2020 17:01:29

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-12T12:01:08', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '200bca8c-f1e1-44e6-a068-11f41d0342b4'	System	12 Aug 2020 17:01:29
User entered 'None (0)'	System	12 Aug 2020 17:01:29

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-12T12:01:10', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '200bca8c-f1e1-44e6-a068-11f41d0342b4'	System	12 Aug 2020 17:01:29
User entered 'None (0)'	System	12 Aug 2020 17:01:29



US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-12T12:01:13', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '200bca8c-f1e1-44e6-a068-11f41d0342b4'	System	12 Aug 2020 17:01:29
User entered 'No (N)'	System	12 Aug 2020 17:01:29

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-12T12:01:16', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '200bca8c-f1e1-44e6-a068-11f41d0342b4'	System	12 Aug 2020 17:01:29
User entered '12 Aug 2020 12:01'	System	12 Aug 2020 17:01:29

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '12 Aug 2020 12:00'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '13 Aug 2020 11:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 6'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-13T12:04:38', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '5a7a0301-5770-441b-baa3-3648c11c0224'	System	13 Aug 2020 17:04:55
User entered 'None (0)'	System	13 Aug 2020 17:04:55

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-13T12:04:39', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '5a7a0301-5770-441b-baa3-3648c11c0224'	System	13 Aug 2020 17:04:55
User entered 'None (0)'	System	13 Aug 2020 17:04:55

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-13T12:04:40', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '5a7a0301-5770-441b-baa3-3648c11c0224'	System	13 Aug 2020 17:04:55
User entered 'None (0)'	System	13 Aug 2020 17:04:55



US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-13T12:04:42', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '5a7a0301-5770-441b-baa3-3648c11c0224'	System	13 Aug 2020 17:04:55
User entered 'None (0)'	System	13 Aug 2020 17:04:55

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-13T12:04:43', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '5a7a0301-5770-441b-baa3-3648c11c0224'	System	13 Aug 2020 17:04:55
User entered 'None (0)'	System	13 Aug 2020 17:04:55

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-13T12:04:44', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '5a7a0301-5770-441b-baa3-3648c11c0224'	System	13 Aug 2020 17:04:55
User entered 'None (0)'	System	13 Aug 2020 17:04:55

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-13T12:04:48', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '5a7a0301-5770-441b-baa3-3648c11c0224'	System	13 Aug 2020 17:04:55
User entered 'No (N)'	System	13 Aug 2020 17:04:55

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-13T12:04:52', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '5a7a0301-5770-441b-baa3-3648c11c0224'	System	13 Aug 2020 17:04:55
User entered '13 Aug 2020 12:04'	System	13 Aug 2020 17:04:55

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '13 Aug 2020 12:00'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '14 Aug 2020 11:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 7'	System	08 Aug 2020 15:20:03



US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-14T12:00:48', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '8872d672-6bf0-4061-8eab-3d2672d64ddb'	System	14 Aug 2020 17:01:13
User entered 'None (0)'	System	14 Aug 2020 17:01:13

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-14T12:00:50', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '8872d672-6bf0-4061-8eab-3d2672d64ddb'	System	14 Aug 2020 17:01:13
User entered 'None (0)'	System	14 Aug 2020 17:01:13

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-14T12:00:52', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '8872d672-6bf0-4061-8eab-3d2672d64ddb'	System	14 Aug 2020 17:01:13
User entered 'None (0)'	System	14 Aug 2020 17:01:13

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-14T12:00:53', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '8872d672-6bf0-4061-8eab-3d2672d64ddb'	System	14 Aug 2020 17:01:13
User entered 'None (0)'	System	14 Aug 2020 17:01:13

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-14T12:00:54', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '8872d672-6bf0-4061-8eab-3d2672d64ddb'	System	14 Aug 2020 17:01:13
User entered 'None (0)'	System	14 Aug 2020 17:01:13

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-14T12:00:55', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '8872d672-6bf0-4061-8eab-3d2672d64ddb'	System	14 Aug 2020 17:01:13
User entered 'None (0)'	System	14 Aug 2020 17:01:13

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-14T12:00:56', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '8872d672-6bf0-4061-8eab-3d2672d64ddb'	System	14 Aug 2020 17:01:13
User entered 'No (N)'	System	14 Aug 2020 17:01:13

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-08-14T12:00:59', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '8872d672-6bf0-4061-8eab-3d2672d64ddb'	System	14 Aug 2020 17:01:13
User entered '14 Aug 2020 12:00'	System	14 Aug 2020 17:01:13



US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '14 Aug 2020 12:00'	System	08 Aug 2020 15:20:03

US3812085

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '15 Aug 2020 11:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	15 Aug 2020 18:48:38

US3812085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '15 Aug 2020'	Breanna Galibert (b) (4)	15 Aug 2020 18:48:38

US3812085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4)	15 Aug 2020 18:48:38

US3812085

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Breanna Galibert (b) (4)	15 Aug 2020 18:48:38

US3812085

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Angie Kean (b) (4)	25 Aug 2020 17:22:11

**US3812085**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'I'	System	25 Aug 2020 17:22:11



US3812085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Angie Kean (b) (4)	25 Aug 2020 17:22:29

US3812085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '23 Aug 2020'	Angie Kean (b) (4)	25 Aug 2020 17:22:29

US3812085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Contact Made (CONTACT MADE)'	Angie Kean (b) (4)	25 Aug 2020 17:22:29

US3812085

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Angie Kean (b) (4)	25 Aug 2020 17:22:29

US3812085

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Angie Kean (b) (4)	29 Aug 2020 18:05:42

**US3812085**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'I'	System	29 Aug 2020 18:05:42

**US3812085**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:27**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Maureen Dempsey (b) (4)	03 Sep 2020 17:34:49

US3812085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '29 Aug 2020'	Maureen Dempsey (b) (4)	03 Sep 2020 17:34:49



US3812085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Contact Made (CONTACT MADE)'	Maureen Dempsey (b) (4)	03 Sep 2020 17:34:49

US3812085

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Maureen Dempsey (b) (4)	03 Sep 2020 17:34:49

US3812085

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	02 Sep 2020 23:21:04

**US3812085**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'I'	System	02 Sep 2020 23:21:04

US3812085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:55:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	02 Sep 2020 23:21:12

US3812085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:55:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '02 Sep 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	11 Nov 2020 00:22:01
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 09:29:41
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 22:45:11
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 23:21:12
User entered '2 Sep 2020'	Breanna Galibert (b) (4)	02 Sep 2020 23:21:12

US3812085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:55:27

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	02 Sep 2020 23:21:12

US3812085

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:55:27

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'VISIT2'	System	02 Sep 2020 23:21:12



US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User accepted default value 'Pre-Dose (PREDOSE)'	Breanna Galibert (b) (4) (b) (4)	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 00:22:15
User entered '2 Sep 2020'	(b) (4)	
	Breanna Galibert (b) (4)	09 Sep 2020 14:41:44
	(b) (4)	

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User closed query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	
	System	11 Nov 2020 00:22:32
User opened query 'Pre-dose vital signs time is not prior to the Dose Time. Please review and reconcile.' (Site from System).	System	11 Nov 2020 00:22:27
User entered '16:56'	Breanna Galibert (b) (4)	09 Sep 2020 14:41:44
	(b) (4)	

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered '02 Sep 2020 16:56'	System	11 Nov 2020 00:22:15
User entered '2 Sep 2020 16:56'	System	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '97.6' F	Breanna Galibert (b) (4)	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Breanna Galibert (b) (4)	09 Sep 2020 14:41:44



US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '68'	Breanna Galibert (b) (4)	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'bpm'	System	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '16'	Breanna Galibert (b) (4)	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'breaths/min'	System	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '102'	Breanna Galibert (b) (4)	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'mmHg'	System	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '62'	Breanna Galibert (b) (4)	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:55:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'mmHg'	System	09 Sep 2020 14:41:44



US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User accepted default value 'Post-Dose (POSTDOSE)'	Breanna Galibert (b) (4) (b) (4)	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '02 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 00:22:15
User entered '2 Sep 2020'	(b) (4)	
	Breanna Galibert (b) (4)	09 Sep 2020 14:41:44
	(b) (4)	

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '18:30'	Breanna Galibert (b) (4)	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered '02 Sep 2020 18:30'	System	11 Nov 2020 00:22:15
User entered '2 Sep 2020 18:30'	System	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '97.7' F	Breanna Galibert (b) (4)	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Breanna Galibert (b) (4)	09 Sep 2020 14:41:44



US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '60'	Breanna Galibert (b) (4)	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'bpm'	System	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '14'	Breanna Galibert (b) (4)	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'breaths/min'	System	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '110'	Breanna Galibert (b) (4)	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'mmHg'	System	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '72'	Breanna Galibert (b) (4)	09 Sep 2020 14:41:44

US3812085

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:55:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'mmHg'	System	09 Sep 2020 14:41:44



US3812085

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:55:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'No (N)'	Breanna Galibert (b) (4)	02 Sep 2020 23:22:10

US3812085

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:55:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Breanna Galibert (b) (4)	02 Sep 2020 23:22:10

US3812085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:55:27

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	02 Sep 2020 23:21:32

US3812085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:55:27

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Breanna Galibert (b) (4)	02 Sep 2020 23:21:32

US3812085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Breanna Galibert (b) (4)	02 Sep 2020 23:21:32

US3812085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:55:27

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'MRNA-1273 OR PLACEBO'	System	02 Sep 2020 23:21:32

US3812085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:55:27

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User closed query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	11 Nov 2020 00:22:32
Query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' answered by data change (Site from System).	System	11 Nov 2020 00:22:32
User entered '02 Sep 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	11 Nov 2020 00:22:32
User opened query 'The Treatment Date is not equal to the Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	11 Nov 2020 00:22:27
User entered '01 Sep 2020' reason for change: Data Entry Error	System	11 Nov 2020 00:22:27
User entered '2 Sep 2020'	Maureen Dempsey (b) (4)	11 Nov 2020 00:22:27
	(b) (4)	
	Breanna Galibert (b) (4)	02 Sep 2020 23:21:32
	(b) (4)	

US3812085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:55:27

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '17:57'	Breanna Galibert (b) (4)	02 Sep 2020 23:21:32



US3812085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:55:27

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered '02 Sep 2020 17:57'	System	11 Nov 2020 00:22:32
User entered '01 Sep 2020 17:57'	System	11 Nov 2020 00:22:27
User entered '2 Sep 2020 17:57'	System	02 Sep 2020 23:21:32

US3812085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:55:27

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Left Arm (LEFT ARM)'	Breanna Galibert (b) (4)	02 Sep 2020 23:21:32

US3812085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:55:27

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'ONCE'	System	02 Sep 2020 23:21:32

US3812085

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:55:27

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'INTRAMUSCULAR'	System	02 Sep 2020 23:21:32

US3812085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	02 Sep 2020 23:21:47

US3812085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
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) (4), (b) (6)	11 Nov 2020 12:33:49
User entered '02 Sep 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4)	11 Nov 2020 00:22:41
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. UNSCHEDULE KIT WAS USED PER SPONSOR DUE TO NO SUPPLIES AVAILABLE ON SITE. PPD WAS NOTIFIED TO UPDATE' (Site from DM).	Angie Kean (b) (4)	26 Oct 2020 15:29:30
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 11:59:33
User entered '2 Sep 2020'	Breanna Galibert (b) (4)	02 Sep 2020 23:21:47

US3812085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '17:45'	Breanna Galibert (b) (4)	02 Sep 2020 23:21:47

US3812085

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered '02 Sep 2020 17:45'	System	11 Nov 2020 00:22:41
User entered '2 Sep 2020 17:45'	System	02 Sep 2020 23:21:47



US3812085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:55:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 02SEP2020 is recorded under Visit 2 Day 29 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) (4), (b) (6)	01 Dec 2020 06:58:58
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 02SEP2020 is recorded under Visit 2 Day 29 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. GCL WAS NOTIFIED TO UPDATE' (Site from DM).	Angie Kean (b) (4) (b) (4)	20 Nov 2020 17:50:44
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 02SEP2020 is recorded under Visit 2 Day 29 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)	19 Nov 2020 04:15:24
User entered '02 Sep 2020' reason for change: Data Entry Error	Maureen Dempsey (b) (4) (b) (4)	11 Nov 2020 00:22:48
User closed query 'Per GCL Lab Recon: GCL has this sample as an Unscheduled Sample. Please confirm that 02SEP2020 is Day 29 or clarify' (Site from DM).	(b) (4), (b) (6)	09 Nov 2020 02:10:21
Query 'Per GCL Lab Recon: GCL has this sample as an Unscheduled Sample. Please confirm that 02SEP2020 is Day 29 or clarify' answered with 'DATA IS CORRECT. UNSCHEDULED LAB KIT USED PER SPONSOR. PPD WAS NOTIFIED TO UPDATE' (Site from DM).	Angie Kean (b) (4) (b) (4)	27 Oct 2020 20:46:10

US3812085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:55:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Recon: GCL has this sample as an Unscheduled Sample. Please confirm that 02SEP2020 is Day 29 or clarify' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 19:23:37
Query 'Per GCL Lab Reconciliation: Unscheduled visit has been received by Central Lab with date 03 Sep 2020. However only Visit 2 Day 29 visit for the 02 Sep 2020 is present, please confirm and update accordingly. ' canceled (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 19:23:27
User opened query 'Per GCL Lab Reconciliation: Unscheduled visit has been received by Central Lab with date 03 Sep 2020. However only Visit 2 Day 29 visit for the 02 Sep 2020 is present, please confirm and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 22:07:50
User entered '2 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	02 Sep 2020 23:21:59

US3812085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:55:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Breanna Galibert (b) (4) (b) (4)	02 Sep 2020 23:21:59

US3812085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:55:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	02 Sep 2020 23:21:59

US3812085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:55:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '17:48'	Breanna Galibert (b) (4)	02 Sep 2020 23:21:59

**US3812085**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered '02 Sep 2020 17:48'	System	11 Nov 2020 00:22:48
User entered '2 Sep 2020 17:48'	System	02 Sep 2020 23:21:59

US3812085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:55:27

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Breanna Galibert (b) (4) (b) (4)	02 Sep 2020 23:21:59

US3812085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:55:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'No (N)'	Breanna Galibert (b) (4)	02 Sep 2020 23:21:59



US3812085

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:55:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Breanna Galibert (b) (4)	02 Sep 2020 23:21:59

**US3812085**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:55:27**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered empty.	System	02 Sep 2020 23:21:59

US3812085

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Karen Knapp (b) (4)	09 Sep 2020 17:05:33

US3812085

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:27

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered '1'	System	09 Sep 2020 17:05:33

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03



US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '02 Sep 2020 18:17'	System	11 Nov 2020 00:22:32
User entered '01 Sep 2020 18:17'	System	11 Nov 2020 00:22:27
User entered '02 Sep 2020 18:17'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '02 Sep 2020 20:47'	System	11 Nov 2020 00:22:32
User entered '01 Sep 2020 20:47'	System	11 Nov 2020 00:22:27
User entered '02 Sep 2020 20:47'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-02T22:01:23', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '096f7ba8-c160-4421-9dff-f714f5a5f56f'	System	03 Sep 2020 03:01:42
User entered 'Yes (Y)'	System	03 Sep 2020 03:01:42

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-02T22:01:29', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '096f7ba8-c160-4421-9dff-f714f5a5f56f' User entered '97.5'	System	03 Sep 2020 03:01:42
	System	03 Sep 2020 03:01:42



US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-02T22:01:33', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '096f7ba8-c160-4421-9dff-f714f5a5f56f'	System	03 Sep 2020 03:01:42
User entered 'No (N)'	System	03 Sep 2020 03:01:42

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-02T22:01:38', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '096f7ba8-c160-4421-9dff-f714f5a5f56f' User entered '02 Sep 2020 22:01'	System	03 Sep 2020 03:01:42
	System	03 Sep 2020 03:01:42

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '02 Sep 2020 21:42'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 2'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-03T13:28:27', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'f1068173-9567-40f3-a555-dcf317853638'	System	03 Sep 2020 18:28:44
User entered 'Yes (Y)'	System	03 Sep 2020 18:28:44

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-03T13:28:31', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'f1068173-9567-40f3-a555-dcf317853638'	System	03 Sep 2020 18:28:44
User entered '101.7'	System	03 Sep 2020 18:28:44

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-03T13:28:36', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'f1068173-9567-40f3-a555-dcf317853638'	System	03 Sep 2020 18:28:44
User entered 'No (N)'	System	03 Sep 2020 18:28:44



US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-03T13:28:40', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'f1068173-9567-40f3-a555-dcf317853638'	System	03 Sep 2020 18:28:44
User entered '03 Sep 2020 13:28'	System	03 Sep 2020 18:28:44

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 3'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-04T12:02:25', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'f206d9ff-2838-4a22-9ade-f075536c0d74'	System	04 Sep 2020 17:03:49
User entered 'Yes (Y)'	System	04 Sep 2020 17:03:49

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-04T12:02:30', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'f206d9ff-2838-4a22-9ade-f075536c0d74'	System	04 Sep 2020 17:03:49
User entered '100.0'	System	04 Sep 2020 17:03:49

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-04T12:02:32', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'f206d9ff-2838-4a22-9ade-f075536c0d74'	System	04 Sep 2020 17:03:49
User entered 'Yes (Y)'	System	04 Sep 2020 17:03:49

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'subject was contacted' (Site from System).	(b) (4), (b) (6)	28 Sep 2020 09:56:18
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Karen Knapp (b) (4)	20 Sep 2020 17:27:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-04T12:02:38', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'f206d9ff-2838-4a22-9ade-f075536c0d74'	(b) (4)	
User entered '1'	System	04 Sep 2020 17:03:49
	System	04 Sep 2020 17:03:49
	System	04 Sep 2020 17:03:49



US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:27

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-04T12:02:38', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'f206d9ff-2838-4a22-9ade-f075536c0d74'	System	04 Sep 2020 17:03:49
User entered '0'	System	04 Sep 2020 17:03:49

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-04T12:02:42', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'f206d9ff-2838-4a22-9ade-f075536c0d74'	System	04 Sep 2020 17:03:49
User entered '04 Sep 2020 12:02'	System	04 Sep 2020 17:03:49

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 4'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-05T12:31:37', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '066697fe-29f7-4c9d-beef-f1b657ee754e'	System	05 Sep 2020 17:31:53
User entered 'Yes (Y)'	System	05 Sep 2020 17:31:53

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-05T12:31:42', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '066697fe-29f7-4c9d-beef-f1b657ee754e'	System	05 Sep 2020 17:31:53
User entered '99.0'	System	05 Sep 2020 17:31:53

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-05T12:31:45', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '066697fe-29f7-4c9d-beef-f1b657ee754e'	System	05 Sep 2020 17:31:53
User entered 'No (N)'	System	05 Sep 2020 17:31:53



US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-05T12:31:48', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '066697fe-29f7-4c9d-beef-f1b657ee754e'	System	05 Sep 2020 17:31:53
User entered '05 Sep 2020 12:31'	System	05 Sep 2020 17:31:53

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 5'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-06T12:01:49', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '34594f47-ae39-42b2-87d7-1e796ca659c4'	System	06 Sep 2020 17:02:34
User entered 'Yes (Y)'	System	06 Sep 2020 17:02:34

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-06T12:01:53', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '34594f47-ae39-42b2-87d7-1e796ca659c4'	System	06 Sep 2020 17:02:34
User entered '98.8'	System	06 Sep 2020 17:02:34

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-06T12:01:56', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '34594f47-ae39-42b2-87d7-1e796ca659c4'	System	06 Sep 2020 17:02:34
User entered 'No (N)'	System	06 Sep 2020 17:02:34

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-06T12:02:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '34594f47-ae39-42b2-87d7-1e796ca659c4'	System	06 Sep 2020 17:02:34
User entered '06 Sep 2020 12:02'	System	06 Sep 2020 17:02:34



US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 6'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-07T12:00:24', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '6f4b56bb-2e18-431e-ae3e-c52126eb9c81'	System	07 Sep 2020 17:00:47
User entered 'Yes (Y)'	System	07 Sep 2020 17:00:47

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-07T12:00:28', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '6f4b56bb-2e18-431e-ae3e-c52126eb9c81'	System	07 Sep 2020 17:00:47
User entered '98.6'	System	07 Sep 2020 17:00:47

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-07T12:00:31', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '6f4b56bb-2e18-431e-ae3e-c52126eb9c81'	System	07 Sep 2020 17:00:47
User entered 'No (N)'	System	07 Sep 2020 17:00:47

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-07T12:00:34', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '6f4b56bb-2e18-431e-ae3e-c52126eb9c81'	System	07 Sep 2020 17:00:47
User entered '07 Sep 2020 12:00'	System	07 Sep 2020 17:00:47

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 23:21:32



US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 7'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:27

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-08T12:02:32', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ad845b15-d944-4150-9688-f4202918d396'	System	08 Sep 2020 17:04:07
User entered 'Yes (Y)'	System	08 Sep 2020 17:04:07

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:27

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-08T12:02:36', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ad845b15-d944-4150-9688-f4202918d396'	System	08 Sep 2020 17:04:07
User entered '98.6'	System	08 Sep 2020 17:04:07

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-08T12:02:40', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ad845b15-d944-4150-9688-f4202918d396'	System	08 Sep 2020 17:04:07
User entered 'No (N)'	System	08 Sep 2020 17:04:07

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-08T12:02:45', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ad845b15-d944-4150-9688-f4202918d396'	System	08 Sep 2020 17:04:07
User entered '08 Sep 2020 12:02'	System	08 Sep 2020 17:04:07

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 23:21:32



US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03



US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '02 Sep 2020 18:17'	System	11 Nov 2020 00:22:32
User entered '01 Sep 2020 18:17'	System	11 Nov 2020 00:22:27
User entered '02 Sep 2020 18:17'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '02 Sep 2020 20:47'	System	11 Nov 2020 00:22:32
User entered '01 Sep 2020 20:47'	System	11 Nov 2020 00:22:27
User entered '02 Sep 2020 20:47'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-02T22:01:50', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '8bfe9b07-9a62-4df9-8d69-165b8043294d'	System	03 Sep 2020 03:02:19
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 03:02:19

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-02T22:01:53', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '8bfe9b07-9a62-4df9-8d69-165b8043294d'	System	03 Sep 2020 03:02:19
User entered 'No (N)'	System	03 Sep 2020 03:02:19

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-02T22:02:05', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '8bfe9b07-9a62-4df9-8d69-165b8043294d'	System	03 Sep 2020 03:02:19
User entered 'No (N)'	System	03 Sep 2020 03:02:19

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-02T22:02:12', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '8bfe9b07-9a62-4df9-8d69-165b8043294d'	System	03 Sep 2020 03:02:19
User entered 'None (1)'	System	03 Sep 2020 03:02:19

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-02T22:02:17', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '8bfe9b07-9a62-4df9-8d69-165b8043294d'	System	03 Sep 2020 03:02:19
User entered '02 Sep 2020 22:02'	System	03 Sep 2020 03:02:19



US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '02 Sep 2020 21:42'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 2'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-03T13:28:55', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '17d618a0-86cb-48d1-afcf-486a0da24ab5'	System	03 Sep 2020 18:29:23
User entered 'Does not interfere with activity (2)'	System	03 Sep 2020 18:29:23

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-03T13:28:58', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '17d618a0-86cb-48d1-afcf-486a0da24ab5'	System	03 Sep 2020 18:29:23
User entered 'No (N)'	System	03 Sep 2020 18:29:23

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-03T13:29:04', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '17d618a0-86cb-48d1-afcf-486a0da24ab5'	System	03 Sep 2020 18:29:23
User entered 'No (N)'	System	03 Sep 2020 18:29:23

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-03T13:29:14', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '17d618a0-86cb-48d1-afcf-486a0da24ab5'	System	03 Sep 2020 18:29:23
User entered 'None (1)'	System	03 Sep 2020 18:29:23

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-03T13:29:21', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '17d618a0-86cb-48d1-afcf-486a0da24ab5'	System	03 Sep 2020 18:29:23
User entered '03 Sep 2020 13:29'	System	03 Sep 2020 18:29:23



US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 3'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-04T12:02:47', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '986daa9a-7000-4b0c-b931-7d1f0f72a399'	System	04 Sep 2020 17:04:04
User entered 'None (1)'	System	04 Sep 2020 17:04:04

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-04T12:02:50', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '986daa9a-7000-4b0c-b931-7d1f0f72a399'	System	04 Sep 2020 17:04:04
User entered 'No (N)'	System	04 Sep 2020 17:04:04

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-04T12:02:56', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '986daa9a-7000-4b0c-b931-7d1f0f72a399'	System	04 Sep 2020 17:04:04
User entered 'No (N)'	System	04 Sep 2020 17:04:04

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-04T12:02:58', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '986daa9a-7000-4b0c-b931-7d1f0f72a399'	System	04 Sep 2020 17:04:04
User entered 'None (1)'	System	04 Sep 2020 17:04:04

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-04T12:03:01', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '986daa9a-7000-4b0c-b931-7d1f0f72a399'	System	04 Sep 2020 17:04:04
User entered '04 Sep 2020 12:03'	System	04 Sep 2020 17:04:04



US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 4'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-05T12:31:56', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'c576aff5-d1b3-4594-ab52-5a3367a0ac4f'	System	05 Sep 2020 17:32:14
User entered 'None (1)'	System	05 Sep 2020 17:32:14

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-05T12:32:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'c576aff5-d1b3-4594-ab52-5a3367a0ac4f'	System	05 Sep 2020 17:32:14
User entered 'No (N)'	System	05 Sep 2020 17:32:14

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-05T12:32:04', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'c576aff5-d1b3-4594-ab52-5a3367a0ac4f'	System	05 Sep 2020 17:32:14
User entered 'No (N)'	System	05 Sep 2020 17:32:14

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-05T12:32:07', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'c576aff5-d1b3-4594-ab52-5a3367a0ac4f'	System	05 Sep 2020 17:32:14
User entered 'None (1)'	System	05 Sep 2020 17:32:14

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-05T12:32:11', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'c576aff5-d1b3-4594-ab52-5a3367a0ac4f'	System	05 Sep 2020 17:32:14
User entered '05 Sep 2020 12:32'	System	05 Sep 2020 17:32:14



US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 5'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-06T12:02:04', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '8519d22a-9516-4807-b069-6a3fe6113bed'	System	06 Sep 2020 17:02:46
User entered 'None (1)'	System	06 Sep 2020 17:02:46

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-06T12:02:06', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '8519d22a-9516-4807-b069-6a3fe6113bed'	System	06 Sep 2020 17:02:46
User entered 'No (N)'	System	06 Sep 2020 17:02:46

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-06T12:02:08', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '8519d22a-9516-4807-b069-6a3fe6113bed'	System	06 Sep 2020 17:02:46
User entered 'No (N)'	System	06 Sep 2020 17:02:46

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-06T12:02:10', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '8519d22a-9516-4807-b069-6a3fe6113bed'	System	06 Sep 2020 17:02:46
User entered 'None (1)'	System	06 Sep 2020 17:02:46

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-06T12:02:13', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '8519d22a-9516-4807-b069-6a3fe6113bed' User entered '06 Sep 2020 12:02'	System	06 Sep 2020 17:02:46
	System	06 Sep 2020 17:02:46



US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 6'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-07T12:00:39', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'efc1de7d-c135-47b4-a227-e7e26ee33eba'	System	07 Sep 2020 17:01:13
User entered 'None (1)'	System	07 Sep 2020 17:01:13

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-07T12:00:43', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'efc1de7d-c135-47b4-a227-e7e26ee33eba'	System	07 Sep 2020 17:01:13
User entered 'No (N)'	System	07 Sep 2020 17:01:13

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-07T12:00:45', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'efc1de7d-c135-47b4-a227-e7e26ee33eba'	System	07 Sep 2020 17:01:13
User entered 'No (N)'	System	07 Sep 2020 17:01:13

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-07T12:00:46', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'efc1de7d-c135-47b4-a227-e7e26ee33eba'	System	07 Sep 2020 17:01:13
User entered 'None (1)'	System	07 Sep 2020 17:01:13

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-07T12:00:51', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'efc1de7d-c135-47b4-a227-e7e26ee33eba'	System	07 Sep 2020 17:01:13
User entered '07 Sep 2020 12:00'	System	07 Sep 2020 17:01:13



US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 7'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-08T12:02:51', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'd31263dc-9c31-4a64-b361-22022908ea24'	System	08 Sep 2020 17:04:32
User entered 'None (1)'	System	08 Sep 2020 17:04:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:27

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-08T12:02:55', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'd31263dc-9c31-4a64-b361-22022908ea24'	System	08 Sep 2020 17:04:32
User entered 'No (N)'	System	08 Sep 2020 17:04:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-08T12:03:03', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'd31263dc-9c31-4a64-b361-22022908ea24'	System	08 Sep 2020 17:04:32
User entered 'No (N)'	System	08 Sep 2020 17:04:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-08T12:03:05', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'd31263dc-9c31-4a64-b361-22022908ea24'	System	08 Sep 2020 17:04:32
User entered 'None (1)'	System	08 Sep 2020 17:04:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:27

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-08T12:03:10', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'd31263dc-9c31-4a64-b361-22022908ea24'	System	08 Sep 2020 17:04:32
User entered '08 Sep 2020 12:03'	System	08 Sep 2020 17:04:32



US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03



US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '02 Sep 2020 18:17'	System	11 Nov 2020 00:22:32
User entered '01 Sep 2020 18:17'	System	11 Nov 2020 00:22:27
User entered '02 Sep 2020 18:17'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '02 Sep 2020 20:47'	System	11 Nov 2020 00:22:32
User entered '01 Sep 2020 20:47'	System	11 Nov 2020 00:22:27
User entered '02 Sep 2020 20:47'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 1, after vaccination (at home)'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-02T22:02:27', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1acfa1d0-d269-49d6-94bc-19af7be14d93'	System	03 Sep 2020 03:02:46
User entered 'None (0)'	System	03 Sep 2020 03:02:46

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-02T22:02:28', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1acfa1d0-d269-49d6-94bc-19af7be14d93'	System	03 Sep 2020 03:02:46
User entered 'None (0)'	System	03 Sep 2020 03:02:46



US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-02T22:02:30', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1acfa1d0-d269-49d6-94bc-19af7be14d93'	System	03 Sep 2020 03:02:46
User entered 'None (0)'	System	03 Sep 2020 03:02:46

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-02T22:02:31', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1acfa1d0-d269-49d6-94bc-19af7be14d93'	System	03 Sep 2020 03:02:46
User entered 'None (0)'	System	03 Sep 2020 03:02:46

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-02T22:02:34', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1acfa1d0-d269-49d6-94bc-19af7be14d93'	System	03 Sep 2020 03:02:46
User entered 'None (0)'	System	03 Sep 2020 03:02:46

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-02T22:02:36', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1acfa1d0-d269-49d6-94bc-19af7be14d93'	System	03 Sep 2020 03:02:46
User entered 'None (0)'	System	03 Sep 2020 03:02:46

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-02T22:02:39', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1acfa1d0-d269-49d6-94bc-19af7be14d93'	System	03 Sep 2020 03:02:46
User entered 'No (N)'	System	03 Sep 2020 03:02:46

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-02T22:02:43', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1acfa1d0-d269-49d6-94bc-19af7be14d93'	System	03 Sep 2020 03:02:46
User entered '02 Sep 2020 22:02'	System	03 Sep 2020 03:02:46

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '02 Sep 2020 21:42'	System	02 Sep 2020 23:21:32

**US3812085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:55:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '03 Sep 2020 11:59'	System	02 Sep 2020 23:21:32



US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 2'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-03T13:29:41', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'b50e5a90-5a36-43bd-9c1c-575149699c1c'	System	03 Sep 2020 18:30:34
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	03 Sep 2020 18:30:34

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-03T13:29:47', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'b50e5a90-5a36-43bd-9c1c-575149699c1c'	System	03 Sep 2020 18:30:34
User entered 'Significant; prevents daily activity (3)'	System	03 Sep 2020 18:30:34

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-03T13:29:50', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'b50e5a90-5a36-43bd-9c1c-575149699c1c'	System	03 Sep 2020 18:30:34
User entered 'Significant; prevents daily activity (3)'	System	03 Sep 2020 18:30:34

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-03T13:30:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'b50e5a90-5a36-43bd-9c1c-575149699c1c' User entered 'None (0)'	System	03 Sep 2020 18:30:34
	System	03 Sep 2020 18:30:34

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-03T13:30:07', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'b50e5a90-5a36-43bd-9c1c-575149699c1c' User entered 'None (0)'	System	03 Sep 2020 18:30:34
	System	03 Sep 2020 18:30:34

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-03T13:30:11', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'b50e5a90-5a36-43bd-9c1c-575149699c1c'	System	03 Sep 2020 18:30:34
User entered 'No interference with activity (1)'	System	03 Sep 2020 18:30:34

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-03T13:30:14', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'b50e5a90-5a36-43bd-9c1c-575149699c1c'	System	03 Sep 2020 18:30:34
User entered 'No (N)'	System	03 Sep 2020 18:30:34



US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-03T13:30:27', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'b50e5a90-5a36-43bd-9c1c-575149699c1c' User entered '03 Sep 2020 13:30'	System	03 Sep 2020 18:30:34
	System	03 Sep 2020 18:30:34

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '03 Sep 2020 12:00'	System	02 Sep 2020 23:21:32

**US3812085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:55:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '04 Sep 2020 11:59'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 3'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-04T12:03:10', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'b20245d5-d7ef-4d3a-8f7e-3ec63c8c5bef'	System	04 Sep 2020 17:04:31
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	04 Sep 2020 17:04:31

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-04T12:03:14', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'b20245d5-d7ef-4d3a-8f7e-3ec63c8c5bef'	System	04 Sep 2020 17:04:31
User entered 'Significant; prevents daily activity (3)'	System	04 Sep 2020 17:04:31

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-04T12:03:16', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'b20245d5-d7ef-4d3a-8f7e-3ec63c8c5bef'	System	04 Sep 2020 17:04:31
User entered 'Significant; prevents daily activity (3)'	System	04 Sep 2020 17:04:31

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-04T12:03:20', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'b20245d5-d7ef-4d3a-8f7e-3ec63c8c5bef'	System	04 Sep 2020 17:04:31
User entered 'None (0)'	System	04 Sep 2020 17:04:31



US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-04T12:03:23', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'b20245d5-d7ef-4d3a-8f7e-3ec63c8c5bef'	System	04 Sep 2020 17:04:31
User entered 'None (0)'	System	04 Sep 2020 17:04:31

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-04T12:03:25', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'b20245d5-d7ef-4d3a-8f7e-3ec63c8c5bef'	System	04 Sep 2020 17:04:31
User entered 'No interference with activity (1)'	System	04 Sep 2020 17:04:31

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-04T12:03:32', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'b20245d5-d7ef-4d3a-8f7e-3ec63c8c5bef'	System	04 Sep 2020 17:04:31
User entered 'No (N)'	System	04 Sep 2020 17:04:31

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-04T12:03:36', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'b20245d5-d7ef-4d3a-8f7e-3ec63c8c5bef'	System	04 Sep 2020 17:04:31
User entered '04 Sep 2020 12:03'	System	04 Sep 2020 17:04:31

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '04 Sep 2020 12:00'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '05 Sep 2020 11:59'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 4'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-05T12:32:14', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '0cdfca25-e544-4840-a8c8-bf9e072b8884'	System	05 Sep 2020 17:32:26
User entered 'None (0)'	System	05 Sep 2020 17:32:26



US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-05T12:32:15', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '0cdfca25-e544-4840-a8c8-bf9e072b8884'	System	05 Sep 2020 17:32:26
User entered 'None (0)'	System	05 Sep 2020 17:32:26

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-05T12:32:16', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '0cdfca25-e544-4840-a8c8-bf9e072b8884'	System	05 Sep 2020 17:32:26
User entered 'None (0)'	System	05 Sep 2020 17:32:26

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-05T12:32:17', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '0cdfca25-e544-4840-a8c8-bf9e072b8884'	System	05 Sep 2020 17:32:26
User entered 'None (0)'	System	05 Sep 2020 17:32:26

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-05T12:32:19', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '0cdfca25-e544-4840-a8c8-bf9e072b8884'	System	05 Sep 2020 17:32:26
User entered 'None (0)'	System	05 Sep 2020 17:32:26

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-05T12:32:20', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '0cdfca25-e544-4840-a8c8-bf9e072b8884'	System	05 Sep 2020 17:32:26
User entered 'None (0)'	System	05 Sep 2020 17:32:26

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-05T12:32:21', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '0cdfca25-e544-4840-a8c8-bf9e072b8884'	System	05 Sep 2020 17:32:26
User entered 'No (N)'	System	05 Sep 2020 17:32:26

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-05T12:32:24', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '0cdfca25-e544-4840-a8c8-bf9e072b8884'	System	05 Sep 2020 17:32:26
User entered '05 Sep 2020 12:32'	System	05 Sep 2020 17:32:26

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '05 Sep 2020 12:00'	System	02 Sep 2020 23:21:32



US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '06 Sep 2020 11:59'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 5'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-06T12:02:17', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a5412763-a75f-42f8-b14b-f20a1c9e884c'	System	06 Sep 2020 17:02:58
User entered 'None (0)'	System	06 Sep 2020 17:02:58

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-06T12:02:18', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a5412763-a75f-42f8-b14b-f20a1c9e884c'	System	06 Sep 2020 17:02:58
User entered 'None (0)'	System	06 Sep 2020 17:02:58

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-06T12:02:19', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a5412763-a75f-42f8-b14b-f20a1c9e884c'	System	06 Sep 2020 17:02:58
User entered 'None (0)'	System	06 Sep 2020 17:02:58

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-06T12:02:20', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a5412763-a75f-42f8-b14b-f20a1c9e884c'	System	06 Sep 2020 17:02:58
User entered 'None (0)'	System	06 Sep 2020 17:02:58

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-06T12:02:21', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a5412763-a75f-42f8-b14b-f20a1c9e884c'	System	06 Sep 2020 17:02:58
User entered 'None (0)'	System	06 Sep 2020 17:02:58

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-06T12:02:22', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a5412763-a75f-42f8-b14b-f20a1c9e884c'	System	06 Sep 2020 17:02:58
User entered 'None (0)'	System	06 Sep 2020 17:02:58



US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-06T12:02:24', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a5412763-a75f-42f8-b14b-f20a1c9e884c'	System	06 Sep 2020 17:02:58
User entered 'No (N)'	System	06 Sep 2020 17:02:58

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-06T12:02:27', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'a5412763-a75f-42f8-b14b-f20a1c9e884c'	System	06 Sep 2020 17:02:58
User entered '06 Sep 2020 12:02'	System	06 Sep 2020 17:02:58

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '06 Sep 2020 12:00'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '07 Sep 2020 11:59'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 6'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-07T12:00:55', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '66542efd-d6a0-4195-a68c-fc808e35d2e0'	System	07 Sep 2020 17:01:28
User entered 'None (0)'	System	07 Sep 2020 17:01:28

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-07T12:00:56', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '66542efd-d6a0-4195-a68c-fc808e35d2e0'	System	07 Sep 2020 17:01:28
User entered 'None (0)'	System	07 Sep 2020 17:01:28

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-07T12:00:57', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '66542efd-d6a0-4195-a68c-fc808e35d2e0'	System	07 Sep 2020 17:01:28
User entered 'None (0)'	System	07 Sep 2020 17:01:28



US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-07T12:00:58', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '66542efd-d6a0-4195-a68c-fc808e35d2e0'	System	07 Sep 2020 17:01:28
User entered 'None (0)'	System	07 Sep 2020 17:01:28

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-07T12:01:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '66542efd-d6a0-4195-a68c-fc808e35d2e0'	System	07 Sep 2020 17:01:28
User entered 'None (0)'	System	07 Sep 2020 17:01:28

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-07T12:01:01', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '66542efd-d6a0-4195-a68c-fc808e35d2e0'	System	07 Sep 2020 17:01:28
User entered 'None (0)'	System	07 Sep 2020 17:01:28

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-07T12:01:02', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '66542efd-d6a0-4195-a68c-fc808e35d2e0'	System	07 Sep 2020 17:01:28
User entered 'No (N)'	System	07 Sep 2020 17:01:28

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-07T12:01:06', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '66542efd-d6a0-4195-a68c-fc808e35d2e0'	System	07 Sep 2020 17:01:28
User entered '07 Sep 2020 12:01'	System	07 Sep 2020 17:01:28

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '07 Sep 2020 12:00'	System	02 Sep 2020 23:21:32

**US3812085**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:55:27**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '08 Sep 2020 11:59'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	02 Sep 2020 23:21:32
User entered 'Day 7'	System	02 Sep 2020 23:21:32



US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-08T12:03:14', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1b5b04fe-3259-4daf-ba4c-3fa4541e9e07'	System	08 Sep 2020 17:04:46
User entered 'None (0)'	System	08 Sep 2020 17:04:46

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-08T12:03:16', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1b5b04fe-3259-4daf-ba4c-3fa4541e9e07'	System	08 Sep 2020 17:04:46
User entered 'None (0)'	System	08 Sep 2020 17:04:46

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-08T12:03:17', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1b5b04fe-3259-4daf-ba4c-3fa4541e9e07'	System	08 Sep 2020 17:04:46
User entered 'None (0)'	System	08 Sep 2020 17:04:46

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-08T12:03:18', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1b5b04fe-3259-4daf-ba4c-3fa4541e9e07'	System	08 Sep 2020 17:04:46
User entered 'None (0)'	System	08 Sep 2020 17:04:46

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-08T12:03:20', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1b5b04fe-3259-4daf-ba4c-3fa4541e9e07'	System	08 Sep 2020 17:04:46
User entered 'None (0)'	System	08 Sep 2020 17:04:46

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-08T12:03:22', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1b5b04fe-3259-4daf-ba4c-3fa4541e9e07'	System	08 Sep 2020 17:04:46
User entered 'None (0)'	System	08 Sep 2020 17:04:46

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-08T12:03:23', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1b5b04fe-3259-4daf-ba4c-3fa4541e9e07'	System	08 Sep 2020 17:04:46
User entered 'No (N)'	System	08 Sep 2020 17:04:46

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-09-08T12:03:29', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1b5b04fe-3259-4daf-ba4c-3fa4541e9e07'	System	08 Sep 2020 17:04:46
User entered '08 Sep 2020 12:03'	System	08 Sep 2020 17:04:46



US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '08 Sep 2020 12:00'	System	02 Sep 2020 23:21:32

US3812085

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:55:27

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
User entered '09 Sep 2020 11:59'	System	02 Sep 2020 23:21:32

US3812085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Karen Knapp (b) (4)	09 Sep 2020 17:05:51

US3812085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '09 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Maureen Dempsey (b) (4)	11 Nov 2020 00:22:55
User entered '9 Sep 2020'	(b) (4)	
	Karen Knapp (b) (4)	09 Sep 2020 17:05:51
	(b) (4)	

US3812085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	09 Sep 2020 17:05:51

US3812085

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Karen Knapp (b) (4)	09 Sep 2020 17:05:51

US3812085

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Karen Knapp (b) (4)	09 Sep 2020 17:06:01

**US3812085**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'I'	System	09 Sep 2020 17:06:01



US3812085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Karen Knapp (b) (4)	16 Sep 2020 18:32:12

US3812085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '16 Sep 2020'	Karen Knapp (b) (4)	16 Sep 2020 18:32:12

US3812085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	16 Sep 2020 18:32:12

US3812085

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Karen Knapp (b) (4)	16 Sep 2020 18:32:12

US3812085

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Karen Knapp (b) (4)	16 Sep 2020 18:32:17

**US3812085**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'I'	System	16 Sep 2020 18:32:17

US3812085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Karen Knapp (b) (4)	23 Sep 2020 21:55:50

US3812085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '23 Sep 2020'	Karen Knapp (b) (4)	23 Sep 2020 21:55:50



US3812085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	23 Sep 2020 21:55:50

US3812085

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Karen Knapp (b) (4)	23 Sep 2020 21:55:50

US3812085

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Karen Knapp (b) (4)	23 Sep 2020 21:55:54

**US3812085**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'I'	System	23 Sep 2020 21:55:54

US3812085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:55:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	13 Oct 2020 14:07:18

US3812085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '30 Sep 2020'	Breanna Galibert (b) (4)	13 Oct 2020 14:07:18

US3812085

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:55:27

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	13 Oct 2020 14:07:18

**US3812085**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:55:27**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'VISIT3'	System	13 Oct 2020 14:07:18



US3812085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	13 Oct 2020 14:07:49

US3812085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '30 Sep 2020'	Breanna Galibert (b) (4)	13 Oct 2020 14:07:49

US3812085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '16:14'	Breanna Galibert (b) (4)	13 Oct 2020 14:07:49

**US3812085**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:27**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered '30 Sep 2020 16:14'	System	13 Oct 2020 14:07:49

US3812085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '97.3' F	Breanna Galibert (b) (4)	13 Oct 2020 14:07:49

US3812085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	13 Oct 2020 14:07:49

US3812085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Breanna Galibert (b) (4)	13 Oct 2020 14:07:49

US3812085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '74'	Breanna Galibert (b) (4)	13 Oct 2020 14:07:49



**US3812085**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:27**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'bpm'	System	13 Oct 2020 14:07:49

US3812085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '16'	Breanna Galibert (b) (4)	13 Oct 2020 14:07:49

US3812085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'breaths/min'	System	13 Oct 2020 14:07:49

US3812085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '108'	Breanna Galibert (b) (4)	13 Oct 2020 14:07:49

US3812085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'mmHg'	System	13 Oct 2020 14:07:49

US3812085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '78'	Breanna Galibert (b) (4)	13 Oct 2020 14:07:49

US3812085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'mmHg'	System	13 Oct 2020 14:07:49

US3812085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37



US3812085

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37

US3812085

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:55:27

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'No (N)'	Breanna Galibert (b) (4)	13 Oct 2020 14:08:01

US3812085

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:55:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Breanna Galibert (b) (4)	13 Oct 2020 14:08:01

US3812085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	13 Oct 2020 14:08:14

US3812085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30Sep2020 is recorded under Visit 3 Day 57 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) (4), (b) (6)	27 Nov 2020 12:53:17
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30Sep2020 is recorded under Visit 3 Day 57 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. UNSCHEDULE KIT WAS USED PER SPONSOR DUE TO NO SUPPLIES AVAILABLE ON SITE. PPD WAS NOTIFIED TO UPDATE' (Site from DM).	Angie Kean (b) (4) (b) (4)	26 Oct 2020 15:29:36
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 30Sep2020 is recorded under Visit 3 Day 57 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 12:29:32
User entered '30 Sep 2020'	Breanna Galibert (b) (4) (b) (4)	13 Oct 2020 14:08:14

US3812085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '16:25'	Breanna Galibert (b) (4)	13 Oct 2020 14:08:14

US3812085

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered '30 Sep 2020 16:25'	System	13 Oct 2020 14:08:14

US3812085

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Karen Knapp (b) (4)	18 Oct 2020 15:34:19



**US3812085**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'I'	System	18 Oct 2020 15:34:19

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 64'	System	08 Aug 2020 15:20:03

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09



US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09



US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09
Data entry locked.	System	08 Aug 2020 15:20:03
User entered '08 Oct 2020 00:01'	System	08 Aug 2020 15:20:03

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 16:33:09
Data entry locked.	System	08 Aug 2020 15:20:03
User entered '12 Oct 2020 23:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 71'	System	08 Aug 2020 15:20:03

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-10-15T00:01:25', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '05658b61-ca99-4c07-8b0f-a7ce27cb3dd3'	System	15 Oct 2020 05:01:37
User entered 'No (N)'	System	15 Oct 2020 05:01:37

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

Have you been exposed to someone with 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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-10-15T00:01:28', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '05658b61-ca99-4c07-8b0f-a7ce27cb3dd3'	System	15 Oct 2020 05:01:37
User entered 'No (N)'	System	15 Oct 2020 05:01:37



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-10-15T00:01:31', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '05658b61-ca99-4c07-8b0f-a7ce27cb3dd3'	System	15 Oct 2020 05:01:37
User entered '15 Oct 2020 00:01:31'	System	15 Oct 2020 05:01:37

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered '15 Oct 2020 00:01'	System	08 Aug 2020 15:20:03

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered '19 Oct 2020 23:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 78'	System	08 Aug 2020 15:20:03

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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 23:44:03
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 20:01:04
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'AE updated' (Site from DM).	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:26:45
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 16:29:04
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-10-26T09:23:02', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '6e0b22c3-4982-4a46-9116-46d010ad1e38'	System	26 Oct 2020 14:23:46
User entered 'Yes (Y)'	System	26 Oct 2020 14:23:46

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

Have you been exposed to someone with 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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-10-26T09:23:05', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '6e0b22c3-4982-4a46-9116-46d010ad1e38'	System	26 Oct 2020 14:23:46
User entered 'No (N)'	System	26 Oct 2020 14:23:46

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-10-26T09:23:13', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '6e0b22c3-4982-4a46-9116-46d010ad1e38'	System	26 Oct 2020 14:23:46
User entered 'No (N)'	System	26 Oct 2020 14:23:46

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-10-26T09:23:21', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '6e0b22c3-4982-4a46-9116-46d010ad1e38'	System	26 Oct 2020 14:23:46
User entered 'Yes (Y)'	System	26 Oct 2020 14:23:46



US3812085

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-10-26T09:23:31', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '6e0b22c3-4982-4a46-9116-46d010ad1e38'	System	26 Oct 2020 14:23:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	26 Oct 2020 14:23:46

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-10-26T09:23:34', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '6e0b22c3-4982-4a46-9116-46d010ad1e38' User entered '26 Oct 2020 09:23:34'	System	26 Oct 2020 14:23:46
	System	26 Oct 2020 14:23:46

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered '22 Oct 2020 00:01'	System	08 Aug 2020 15:20:03

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered '26 Oct 2020 23:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 92'	System	08 Aug 2020 15:20:03

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-11-07T14:54:56', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '4869cf1a-4c63-4227-8120-a8e2c841e118'	System	07 Nov 2020 20:55:24
User entered 'No (N)'	System	07 Nov 2020 20:55:24

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

Have you been exposed to someone with 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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-11-07T14:55:02', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '4869cf1a-4c63-4227-8120-a8e2c841e118'	System	07 Nov 2020 20:55:24
User entered 'Yes (Y)'	System	07 Nov 2020 20:55:24

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-11-07T14:55:11', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '4869cf1a-4c63-4227-8120-a8e2c841e118'	System	07 Nov 2020 20:55:24
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Nov 2020 20:55:24



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-11-07T14:55:15', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '4869cf1a-4c63-4227-8120-a8e2c841e118'	System	07 Nov 2020 20:55:24
User entered '07 Nov 2020 14:55:15'	System	07 Nov 2020 20:55:24

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered '05 Nov 2020 00:01'	System	08 Aug 2020 15:20:03

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered '09 Nov 2020 23:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 99'	System	08 Aug 2020 15:20:03

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-11-12T02:30:20', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ecf84163-218c-43eb-83ae-72613975b676'	System	12 Nov 2020 08:30:32
User entered 'No (N)'	System	12 Nov 2020 08:30:32

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

Have you been exposed to someone with 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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-11-12T02:30:26', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ecf84163-218c-43eb-83ae-72613975b676'	System	12 Nov 2020 08:30:32
User entered 'No (N)'	System	12 Nov 2020 08:30:32

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-11-12T02:30:29', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ecf84163-218c-43eb-83ae-72613975b676'	System	12 Nov 2020 08:30:32
User entered '12 Nov 2020 02:30:29'	System	12 Nov 2020 08:30:32

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered '12 Nov 2020 00:01'	System	08 Aug 2020 15:20:03



US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered '16 Nov 2020 23:59'	System	08 Aug 2020 15:20:03

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered 'Day 106'	System	08 Aug 2020 15:20:03

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-11-19T02:47:55', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '579b73ce-1360-4448-8b9c-fd5a1a6e30c0'	System	19 Nov 2020 08:48:04
User entered 'No (N)'	System	19 Nov 2020 08:48:04

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

Have you been exposed to someone with 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 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-11-19T02:47:58', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '579b73ce-1360-4448-8b9c-fd5a1a6e30c0'	System	19 Nov 2020 08:48:04
User entered 'No (N)'	System	19 Nov 2020 08:48:04

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-11-19T02:48:01', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '579b73ce-1360-4448-8b9c-fd5a1a6e30c0' User entered '19 Nov 2020 02:48:01'	System	19 Nov 2020 08:48:04
	System	19 Nov 2020 08:48:04

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered '19 Nov 2020 00:01'	System	08 Aug 2020 15:20:03

US3812085

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:55:27

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	06 Mar 2021 23:44:03
Data entry locked.	System	08 Aug 2020 15:20:03
User entered '23 Nov 2020 23:59'	System	08 Aug 2020 15:20:03

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 16:33:09



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2020-11-24T10:55:15', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '4da2f44d-fa12-4513-8bba-7c8f79c4dffd'	System	24 Nov 2020 16:55:27
User entered 'No (N)'	System	24 Nov 2020 16:55:27

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2020-11-24T10:55:17', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '4da2f44d-fa12-4513-8bba-7c8f79c4dffd'	System	24 Nov 2020 16:55:27
User entered 'No (N)'	System	24 Nov 2020 16:55:27

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-11-24T10:55:20', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '4da2f44d-fa12-4513-8bba-7c8f79c4dffd'	System	24 Nov 2020 16:55:27
User entered '24 Nov 2020 10:55:20'	System	24 Nov 2020 16:55:27

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '23 Nov 2020 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '27 Nov 2020 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2020-11-30T06:07:16', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1414b9c4-475c-4cde-ae89-96dd0fcac011'	System	30 Nov 2020 12:07:26
User entered 'No (N)'	System	30 Nov 2020 12:07:26

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2020-11-30T06:07:18', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1414b9c4-475c-4cde-ae89-96dd0fcac011'	System	30 Nov 2020 12:07:26
User entered 'No (N)'	System	30 Nov 2020 12:07:26



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-11-30T06:07:22', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '1414b9c4-475c-4cde-ae89-96dd0fcac011'	System	30 Nov 2020 12:07:26
User entered '30 Nov 2020 06:07:22'	System	30 Nov 2020 12:07:26

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '30 Nov 2020 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '04 Dec 2020 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2020-12-07T08:52:17', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '231b95eb-b034-4956-bf10-7638ea9bcff2'	System	07 Dec 2020 14:52:27
User entered 'No (N)'	System	07 Dec 2020 14:52:27

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2020-12-07T08:52:20', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '231b95eb-b034-4956-bf10-7638ea9bcff2'	System	07 Dec 2020 14:52:27
User entered 'No (N)'	System	07 Dec 2020 14:52:27

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-12-07T08:52:22', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '231b95eb-b034-4956-bf10-7638ea9bcff2'	System	07 Dec 2020 14:52:27
User entered '07 Dec 2020 08:52:22'	System	07 Dec 2020 14:52:27

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '07 Dec 2020 00:01'	System	19 Nov 2020 16:33:09



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '11 Dec 2020 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2020-12-14T02:35:47', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'c3e85c97-e3de-46ca-9e28-ba4eed0cd6cd'	System	14 Dec 2020 08:36:00
User entered 'No (N)'	System	14 Dec 2020 08:36:00

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2020-12-14T02:35:51', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'c3e85c97-e3de-46ca-9e28-ba4eed0cd6cd'	System	14 Dec 2020 08:36:00
User entered 'No (N)'	System	14 Dec 2020 08:36:00

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-12-14T02:35:54', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'c3e85c97-e3de-46ca-9e28-ba4eed0cd6cd' User entered '14 Dec 2020 02:35:54'	System	14 Dec 2020 08:36:00
	System	14 Dec 2020 08:36:00

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '14 Dec 2020 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '18 Dec 2020 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 16:33:09



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2020-12-21T01:36:04', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'da427967-c9c6-4105-b9da-3a47dc6faa30'	System	21 Dec 2020 07:36:12
User entered 'No (N)'	System	21 Dec 2020 07:36:12

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2020-12-21T01:36:07', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'da427967-c9c6-4105-b9da-3a47dc6faa30'	System	21 Dec 2020 07:36:12
User entered 'No (N)'	System	21 Dec 2020 07:36:12

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-12-21T01:36:10', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'da427967-c9c6-4105-b9da-3a47dc6faa30'	System	21 Dec 2020 07:36:12
User entered '21 Dec 2020 01:36:10'	System	21 Dec 2020 07:36:12

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '21 Dec 2020 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '25 Dec 2020 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2020-12-28T05:52:48', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '3c0fda51-50aa-4372-9227-efe793d928f0'	System	28 Dec 2020 11:52:59
User entered 'No (N)'	System	28 Dec 2020 11:52:59

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2020-12-28T05:52:51', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '3c0fda51-50aa-4372-9227-efe793d928f0'	System	28 Dec 2020 11:52:59
User entered 'No (N)'	System	28 Dec 2020 11:52:59



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2020-12-28T05:52:56', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '3c0fda51-50aa-4372-9227-efe793d928f0'	System	28 Dec 2020 11:52:59
User entered '28 Dec 2020 05:52:56'	System	28 Dec 2020 11:52:59

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '28 Dec 2020 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '01 Jan 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2021-01-07T12:00:39', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '58c3e20d-0643-46ba-8e17-d6e94d2bd08e'	System	07 Jan 2021 18:00:50
User entered 'No (N)'	System	07 Jan 2021 18:00:50

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2021-01-07T12:00:42', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '58c3e20d-0643-46ba-8e17-d6e94d2bd08e'	System	07 Jan 2021 18:00:50
User entered 'No (N)'	System	07 Jan 2021 18:00:50

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2021-01-07T12:00:47', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '58c3e20d-0643-46ba-8e17-d6e94d2bd08e' User entered '07 Jan 2021 12:00:47'	System	07 Jan 2021 18:00:50
	System	07 Jan 2021 18:00:50

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '04 Jan 2021 00:01'	System	19 Nov 2020 16:33:09



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '08 Jan 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2021-01-11T07:15:10', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'b5a94754-3eee-4e8d-8a80-18d51344e601'	System	11 Jan 2021 13:15:21
User entered 'No (N)'	System	11 Jan 2021 13:15:21

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2021-01-11T07:15:13', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'b5a94754-3eee-4e8d-8a80-18d51344e601'	System	11 Jan 2021 13:15:21
User entered 'No (N)'	System	11 Jan 2021 13:15:21

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2021-01-11T07:15:17', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'b5a94754-3eee-4e8d-8a80-18d51344e601' User entered '11 Jan 2021 07:15:17'	System	11 Jan 2021 13:15:21
	System	11 Jan 2021 13:15:21

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '11 Jan 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '15 Jan 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 16:33:09



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2021-01-21T11:02:28', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'd5642771-9877-4684-b904-47626cb8f1bd'	System	21 Jan 2021 17:02:44
User entered 'No (N)'	System	21 Jan 2021 17:02:44

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2021-01-21T11:02:31', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'd5642771-9877-4684-b904-47626cb8f1bd'	System	21 Jan 2021 17:02:44
User entered 'No (N)'	System	21 Jan 2021 17:02:44

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2021-01-21T11:02:35', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'd5642771-9877-4684-b904-47626cb8f1bd' User entered '21 Jan 2021 11:02:35'	System	21 Jan 2021 17:02:44

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '18 Jan 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '22 Jan 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2021-01-25T00:34:27', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'd97ecf5a-c36e-4be5-a571-a1ba5e74b636'	System	25 Jan 2021 06:34:41
User entered 'No (N)'	System	25 Jan 2021 06:34:41

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2021-01-25T00:34:30', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'd97ecf5a-c36e-4be5-a571-a1ba5e74b636'	System	25 Jan 2021 06:34:41
User entered 'No (N)'	System	25 Jan 2021 06:34:41



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2021-01-25T00:34:34', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'd97ecf5a-c36e-4be5-a571-a1ba5e74b636'	System	25 Jan 2021 06:34:41
User entered '25 Jan 2021 00:34:34'	System	25 Jan 2021 06:34:41

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '25 Jan 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '29 Jan 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2021-02-01T04:48:45', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '13722021-c2a4-4bf3-b636-fb11eea55d3a'	System	01 Feb 2021 10:48:56
User entered 'No (N)'	System	01 Feb 2021 10:48:56

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2021-02-01T04:48:48', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '13722021-c2a4-4bf3-b636-fb11eea55d3a'	System	01 Feb 2021 10:48:56
User entered 'No (N)'	System	01 Feb 2021 10:48:56

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2021-02-01T04:48:51', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '13722021-c2a4-4bf3-b636-fb11eea55d3a'	System	01 Feb 2021 10:48:56
User entered '01 Feb 2021 04:48:51'	System	01 Feb 2021 10:48:56

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '01 Feb 2021 00:01'	System	19 Nov 2020 16:33:09



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '05 Feb 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2021-02-11T10:30:43', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '4f05e34c-8bf3-4398-9ff3-ddcf4d4a6ed6'	System	11 Feb 2021 16:30:53
User entered 'No (N)'	System	11 Feb 2021 16:30:53

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2021-02-11T10:30:45', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '4f05e34c-8bf3-4398-9ff3-ddcf4d4a6ed6'	System	11 Feb 2021 16:30:53
User entered 'No (N)'	System	11 Feb 2021 16:30:53

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2021-02-11T10:30:49', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '4f05e34c-8bf3-4398-9ff3-ddcf4d4a6ed6'	System	11 Feb 2021 16:30:53
User entered '11 Feb 2021 10:30:49'	System	11 Feb 2021 16:30:53

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '08 Feb 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '12 Feb 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 16:33:09



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2021-02-18T06:25:23', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ca847141-f40e-471d-bd16-64689d91f4c0'	System	18 Feb 2021 12:25:32
User entered 'No (N)'	System	18 Feb 2021 12:25:32

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2021-02-18T06:25:25', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ca847141-f40e-471d-bd16-64689d91f4c0'	System	18 Feb 2021 12:25:32
User entered 'No (N)'	System	18 Feb 2021 12:25:32

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2021-02-18T06:25:28', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ca847141-f40e-471d-bd16-64689d91f4c0'	System	18 Feb 2021 12:25:32
User entered '18 Feb 2021 06:25:28'	System	18 Feb 2021 12:25:32

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '15 Feb 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '19 Feb 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2021-02-22T06:35:10', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ce8d0159-f554-46b1-9994-59244034d1e6'	System	22 Feb 2021 12:35:21
User entered 'No (N)'	System	22 Feb 2021 12:35:21

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2021-02-22T06:35:12', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ce8d0159-f554-46b1-9994-59244034d1e6'	System	22 Feb 2021 12:35:21
User entered 'No (N)'	System	22 Feb 2021 12:35:21



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2021-02-22T06:35:15', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'ce8d0159-f554-46b1-9994-59244034d1e6'	System	22 Feb 2021 12:35:21
User entered '22 Feb 2021 06:35:15'	System	22 Feb 2021 12:35:21

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '22 Feb 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '26 Feb 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2021-03-04T11:32:06-06:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '524f1400-9d83-4e63-8e6a-27268dc4a363'	System	04 Mar 2021 17:32:18
User entered 'No (N)'	System	04 Mar 2021 17:32:18

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2021-03-04T11:32:10-06:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '524f1400-9d83-4e63-8e6a-27268dc4a363'	System	04 Mar 2021 17:32:18
User entered 'No (N)'	System	04 Mar 2021 17:32:18

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2021-03-04T11:32:13-06:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '524f1400-9d83-4e63-8e6a-27268dc4a363'	System	04 Mar 2021 17:32:18
User entered '04 Mar 2021 11:32:13'	System	04 Mar 2021 17:32:18

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '01 Mar 2021 00:01'	System	19 Nov 2020 16:33:09



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '05 Mar 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2021-03-10T23:58:34-06:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '4a0adb18-0391-4b41-a23e-6dc5587d174c'	System	11 Mar 2021 05:58:46
User entered 'No (N)'	System	11 Mar 2021 05:58:46

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2021-03-10T23:58:38-06:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '4a0adb18-0391-4b41-a23e-6dc5587d174c'	System	11 Mar 2021 05:58:46
User entered 'No (N)'	System	11 Mar 2021 05:58:46

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2021-03-10T23:58:42-06:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '4a0adb18-0391-4b41-a23e-6dc5587d174c'	System	11 Mar 2021 05:58:46
User entered '10 Mar 2021 23:58:42'	System	11 Mar 2021 05:58:46

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '08 Mar 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '12 Mar 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 16:33:09



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2021-03-18T09:18:50-05:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'c45553de-d4a4-45f2-8f3c-ec9a52f90a1d' User entered 'No (N)'	System	18 Mar 2021 14:18:58
	System	18 Mar 2021 14:18:58

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2021-03-18T09:18:51-05:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'c45553de-d4a4-45f2-8f3c-ec9a52f90a1d'	System	18 Mar 2021 14:18:58
User entered 'No (N)'	System	18 Mar 2021 14:18:58

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2021-03-18T09:18:54-05:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'c45553de-d4a4-45f2-8f3c-ec9a52f90a1d' User entered '18 Mar 2021 09:18:54'	System	18 Mar 2021 14:18:58
	System	18 Mar 2021 14:18:58

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '15 Mar 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '19 Mar 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2021-03-25T09:28:07-05:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '68f13cbe-01d8-4e90-a1fc-7369f54fb29a'	System	25 Mar 2021 14:28:18
User entered 'No (N)'	System	25 Mar 2021 14:28:18

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2021-03-25T09:28:10-05:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '68f13cbe-01d8-4e90-a1fc-7369f54fb29a'	System	25 Mar 2021 14:28:18
User entered 'No (N)'	System	25 Mar 2021 14:28:18



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2021-03-25T09:28:13-05:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '68f13cbe-01d8-4e90-a1fc-7369f54fb29a' User entered '25 Mar 2021 09:28:13'	System	25 Mar 2021 14:28:18
	System	25 Mar 2021 14:28:18

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '22 Mar 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '26 Mar 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2021-03-29T05:18:39-05:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '91a72dbc-a4a2-4d7a-8ef1-2b1254f4d5ed' User entered 'No (N)'	System	29 Mar 2021 10:18:51
	System	29 Mar 2021 10:18:51

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2021-03-29T05:18:43-05:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '91a72dbc-a4a2-4d7a-8ef1-2b1254f4d5ed'	System	29 Mar 2021 10:18:51
User entered 'No (N)'	System	29 Mar 2021 10:18:51

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2021-03-29T05:18:46-05:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '91a72dbc-a4a2-4d7a-8ef1-2b1254f4d5ed' User entered '29 Mar 2021 05:18:46'	System	29 Mar 2021 10:18:51
	System	29 Mar 2021 10:18:51

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '29 Mar 2021 00:01'	System	19 Nov 2020 16:33:09



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '02 Apr 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2021-04-08T09:11:20-05:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '5f07101e-b88e-4af2-9db8-47b54ccc2a48'	System	08 Apr 2021 14:11:37
User entered 'No (N)'	System	08 Apr 2021 14:11:37

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2021-04-08T09:11:24-05:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '5f07101e-b88e-4af2-9db8-47b54ccc2a48'	System	08 Apr 2021 14:11:37
User entered 'No (N)'	System	08 Apr 2021 14:11:37

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2021-04-08T09:11:31-05:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '5f07101e-b88e-4af2-9db8-47b54ccc2a48'	System	08 Apr 2021 14:11:37
User entered '08 Apr 2021 09:11:31'	System	08 Apr 2021 14:11:37

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '05 Apr 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '09 Apr 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 16:33:09



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2021-04-12T05:04:37-05:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '20abf39d-d037-4c6b-8a13-ccb1981fe61b' User entered 'No (N)'	System	12 Apr 2021 10:04:47
	System	12 Apr 2021 10:04:47

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2021-04-12T05:04:40-05:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '20abf39d-d037-4c6b-8a13-ccb1981fe61b'	System	12 Apr 2021 10:04:47
User entered 'No (N)'	System	12 Apr 2021 10:04:47

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2021-04-12T05:04:43-05:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '20abf39d-d037-4c6b-8a13-ccb1981fe61b'	System	12 Apr 2021 10:04:47
User entered '12 Apr 2021 05:04:43'	System	12 Apr 2021 10:04:47

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '12 Apr 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '16 Apr 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2021-04-22T08:15:08-05:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'dbdac364-e70f-4f5c-a195-d8d049688b06'	System	22 Apr 2021 13:15:20
User entered 'No (N)'	System	22 Apr 2021 13:15:20

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2021-04-22T08:15:13-05:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'dbdac364-e70f-4f5c-a195-d8d049688b06'	System	22 Apr 2021 13:15:20
User entered 'No (N)'	System	22 Apr 2021 13:15:20



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2021-04-22T08:15:17-05:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'dbdac364-e70f-4f5c-a195-d8d049688b06'	System	22 Apr 2021 13:15:20
User entered '22 Apr 2021 08:15:17'	System	22 Apr 2021 13:15:20

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '19 Apr 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '23 Apr 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[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 (a18aed58d4c5a666)', Time: '2021-04-26T06:35:39-05:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'afeceddc-ce08-4ac1-a787-e2fec34b918f' User entered 'No (N)'	System	26 Apr 2021 11:35:47

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

Have you been exposed to someone with 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 (a18aed58d4c5a666)', Time: '2021-04-26T06:35:41-05:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'afeceddc-ce08-4ac1-a787-e2fec34b918f' User entered 'No (N)'	System	26 Apr 2021 11:35:47

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2021-04-26T06:35:44-05:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: 'afeceddc-ce08-4ac1-a787-e2fec34b918f' User entered '26 Apr 2021 06:35:44'	System	26 Apr 2021 11:35:47
	System	26 Apr 2021 11:35:47

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '26 Apr 2021 00:01'	System	19 Nov 2020 16:33:09



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '30 Apr 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '03 May 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '07 May 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '10 May 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '14 May 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 16:33:09



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '17 May 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '21 May 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '24 May 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '28 May 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '31 May 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '04 Jun 2021 23:59'	System	19 Nov 2020 16:33:09



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '07 Jun 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '11 Jun 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '14 Jun 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '18 Jun 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '21 Jun 2021 00:01'	System	19 Nov 2020 16:33:09



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '25 Jun 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '28 Jun 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '02 Jul 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '05 Jul 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '09 Jul 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 16:33:09



**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '12 Jul 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '16 Jul 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '19 Jul 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '23 Jul 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '26 Jul 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '30 Jul 2021 23:59'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '02 Aug 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '06 Aug 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '09 Aug 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '13 Aug 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '16 Aug 2021 00:01'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '20 Aug 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '23 Aug 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '27 Aug 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '30 Aug 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '03 Sep 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '06 Sep 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '10 Sep 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '13 Sep 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '17 Sep 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '20 Sep 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '24 Sep 2021 23:59'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '27 Sep 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '01 Oct 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '04 Oct 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '08 Oct 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '11 Oct 2021 00:01'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '15 Oct 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '18 Oct 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '22 Oct 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '25 Oct 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '29 Oct 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '01 Nov 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '05 Nov 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '08 Nov 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '12 Nov 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '15 Nov 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '19 Nov 2021 23:59'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '22 Nov 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '26 Nov 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '29 Nov 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '03 Dec 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '06 Dec 2021 00:01'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '10 Dec 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '13 Dec 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '17 Dec 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '20 Dec 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '24 Dec 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '27 Dec 2021 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '31 Dec 2021 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '03 Jan 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '07 Jan 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '10 Jan 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '14 Jan 2022 23:59'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '17 Jan 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '21 Jan 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '24 Jan 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '28 Jan 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '31 Jan 2022 00:01'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '04 Feb 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '07 Feb 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '11 Feb 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '14 Feb 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '18 Feb 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '21 Feb 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '25 Feb 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '28 Feb 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '04 Mar 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '07 Mar 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '11 Mar 2022 23:59'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '14 Mar 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '18 Mar 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '21 Mar 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '25 Mar 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '28 Mar 2022 00:01'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '01 Apr 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '04 Apr 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '08 Apr 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '11 Apr 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '15 Apr 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '18 Apr 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '22 Apr 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '25 Apr 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '29 Apr 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '02 May 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '06 May 2022 23:59'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '09 May 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '13 May 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '16 May 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '20 May 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '23 May 2022 00:01'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '27 May 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '30 May 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '03 Jun 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '06 Jun 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '10 Jun 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '13 Jun 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '17 Jun 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '20 Jun 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '24 Jun 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '27 Jun 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '01 Jul 2022 23:59'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '04 Jul 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '08 Jul 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '11 Jul 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '15 Jul 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '18 Jul 2022 00:01'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '22 Jul 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '25 Jul 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '29 Jul 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '01 Aug 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '05 Aug 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '08 Aug 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '12 Aug 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '15 Aug 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '19 Aug 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '22 Aug 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '26 Aug 2022 23:59'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '29 Aug 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '02 Sep 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '05 Sep 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '09 Sep 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '12 Sep 2022 00:01'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '16 Sep 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '19 Sep 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '23 Sep 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '26 Sep 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '30 Sep 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 16:33:09



**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '03 Oct 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '07 Oct 2022 23:59'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '10 Oct 2022 00:01'	System	19 Nov 2020 16:33:09

**US3812085**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:55:27**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 16:33:09
Amendment Manager: User entered '14 Oct 2022 23:59'	System	19 Nov 2020 16:33:09

US3812085

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:55:27**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2021-03-04T11:31:49-06:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '89c74718-be69-49de-a8d1-5cb930c50f58'	System	04 Mar 2021 17:32:07
User entered 'No (N)'	System	04 Mar 2021 17:32:07

**US3812085**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 19:30:28
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (a18aed58d4c5a666)', Time: '2021-03-04T11:31:58-06:00', User OID: 'PatientReportedOutcome (US3812085)', ODM File OID: '89c74718-be69-49de-a8d1-5cb930c50f58'	System	04 Mar 2021 17:32:07
User entered '04 Mar 2021 11:31:58'	System	04 Mar 2021 17:32:07

**US3812085**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:27**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Karen Knapp (b) (4)	28 Oct 2020 14:45:31



US3812085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '28 Oct 2020'	Karen Knapp (b) (4)	28 Oct 2020 14:45:31

US3812085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	28 Oct 2020 14:45:31

US3812085

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Karen Knapp (b) (4)	28 Oct 2020 14:45:31

US3812085

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Karen Knapp (b) (4)	28 Oct 2020 14:45:36

**US3812085**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 18:43:37
User entered 'I'	System	28 Oct 2020 14:45:36

**US3812085**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:27**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'Yes (Y)'	Karen Knapp (b) (4)	01 Dec 2020 17:34:24

US3812085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered '1 Dec 2020'	Karen Knapp (b) (4)	01 Dec 2020 17:34:24

US3812085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	01 Dec 2020 17:34:24



US3812085

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered empty.	Karen Knapp (b) (4)	01 Dec 2020 17:34:24

US3812085

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'Yes (Y)'	Karen Knapp (b) (4)	01 Dec 2020 17:34:28

**US3812085**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:42
User entered 'I'	System	01 Dec 2020 17:34:28

**US3812085**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:27**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'Yes (Y)'	Karen Knapp (b) (4)	28 Dec 2020 23:16:18

US3812085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered '28 Dec 2020'	Karen Knapp (b) (4)	28 Dec 2020 23:16:18

US3812085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	28 Dec 2020 23:16:18

US3812085

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered empty.	Karen Knapp (b) (4)	28 Dec 2020 23:16:18

US3812085

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'Yes (Y)'	Karen Knapp (b) (4)	28 Dec 2020 23:16:21



**US3812085**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:42
User entered 'I'	System	28 Dec 2020 23:16:21

US3812085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Karen Knapp (b) (4)	29 Jan 2021 22:01:08

US3812085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered '29 Jan 2021'	Karen Knapp (b) (4)	29 Jan 2021 22:01:08

US3812085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Contact Made (CONTACT MADE)'	Karen Knapp (b) (4)	29 Jan 2021 22:01:08

US3812085

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered empty.	Karen Knapp (b) (4)	29 Jan 2021 22:01:08

US3812085

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:42
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:34
User entered 'Yes (Y)'	Karen Knapp (b) (4)	29 Jan 2021 22:01:12

**US3812085**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 11:53:42
User entered 'I'	System	29 Jan 2021 22:01:12

US3812085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:55:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:49:09
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	23 Mar 2021 13:39:28



US3812085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:55:27

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:49:09
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	31 Mar 2021 07:21:57
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'visit was performed OOW due to subject being out of town. ' (Site from System).	Angie Kean (b) (4)	26 Mar 2021 20:39:04
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	23 Mar 2021 13:39:28
User entered '22 Mar 2021'	Breanna Galibert (b) (4)	23 Mar 2021 13:39:28

US3812085

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:55:27

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 09:01:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:49:09
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	23 Mar 2021 13:39:28

**US3812085**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:55:27**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered 'VISIT4'	System	23 Mar 2021 13:39:28

US3812085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:26:51
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	30 Mar 2021 15:48:35

US3812085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:26:51
User entered '22 Mar 2021'	Breanna Galibert (b) (4)	30 Mar 2021 15:48:35

**US3812085**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:27**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:26:51
User entered '16:31'	Breanna Galibert (b) (4)	30 Mar 2021 15:48:35

**US3812085**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:55:27**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered '22 Mar 2021 16:31'	System	30 Mar 2021 15:48:35

US3812085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:26:51
User entered '98.1' F	Breanna Galibert (b) (4)	30 Mar 2021 15:48:35



US3812085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:26:51
User entered 'Oral (Oral)'	Breanna Galibert (b) (4)	30 Mar 2021 15:48:35

US3812085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:26:51
User entered empty.	Breanna Galibert (b) (4)	30 Mar 2021 15:48:35

US3812085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:26:51
User entered '72'	Breanna Galibert (b) (4)	30 Mar 2021 15:48:35

US3812085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered 'bpm'	System	30 Mar 2021 15:48:35

US3812085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:26:51
User entered '16'	Breanna Galibert (b) (4)	30 Mar 2021 15:48:35

US3812085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered 'breaths/min'	System	30 Mar 2021 15:48:35

US3812085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:26:51
User entered '118'	Breanna Galibert (b) (4)	30 Mar 2021 15:48:35

US3812085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered 'mmHg'	System	30 Mar 2021 15:48:35



US3812085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 01:26:51
User entered '76'	Breanna Galibert (b) (4)	30 Mar 2021 15:48:35

US3812085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered 'mmHg'	System	30 Mar 2021 15:48:35

US3812085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) [REDACTED]	27 Apr 2021 09:01:46

US3812085

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:55:27

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46

US3812085

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:55:27

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	23 Mar 2021 13:39:40

US3812085

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:55:27

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered '22 Mar 2021'	Breanna Galibert (b) (4)	23 Mar 2021 13:39:40

US3812085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	23 Mar 2021 13:39:46

US3812085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:27

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered '22 Mar 2021'	Breanna Galibert (b) (4)	23 Mar 2021 13:39:46



US3812085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered '16:45'	Breanna Galibert (b) (4)	23 Mar 2021 13:39:46

US3812085

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered '22 Mar 2021 16:45'	System	23 Mar 2021 13:39:46

US3812085

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	23 Mar 2021 13:40:05

**US3812085**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 09:01:46
User entered 'I'	System	23 Mar 2021 13:40:05

US3812085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:11
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:49:09
User entered 'Yes (Y)'	Maureen Dempsey (b) (4)	31 Mar 2021 15:11:45

US3812085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:11
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:49:09
User entered '31 Mar 2021'	Maureen Dempsey (b) (4)	31 Mar 2021 15:11:45

**US3812085**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:55:27**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:11
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:49:09
User entered 'Contact Made (CONTACT MADE)'	Maureen Dempsey (b) (4)	31 Mar 2021 15:11:45

US3812085

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:11
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:49:09
User entered empty.	Maureen Dempsey (b) (4)	31 Mar 2021 15:11:45



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Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:11
User signature succeeded.	Lyly Dang (b) (4)	08 Apr 2021 00:49:09
User entered 'Yes (Y)'	Maureen Dempsey (b) (4)	31 Mar 2021 15:11:51

**US3812085**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 21:59:11
User entered 'I'	System	31 Mar 2021 15:11:51

US3812085

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	03 May 2021 19:24:06
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 May 2021 15:19:49
	(b) (4)	

US3812085

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	03 May 2021 19:24:06
User entered '30 Apr 2021'	Breanna Galibert (b) (4)	03 May 2021 15:19:49
	(b) (4)	

US3812085

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	03 May 2021 19:24:06
User entered 'Contact Made (CONTACT MADE)'	Breanna Galibert (b) (4)	03 May 2021 15:19:49
	(b) (4)	

US3812085

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:55:27

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	03 May 2021 19:24:06
User entered empty.	Breanna Galibert (b) (4)	03 May 2021 15:19:49
	(b) (4)	

US3812085

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:55:27

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	03 May 2021 19:24:06
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	03 May 2021 15:19:51
	(b) (4)	

**US3812085**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:55:27**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 15:19:51



US3812085

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 10 Jun 2021 09:55:27

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 21:46:31
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'No (N)'	Karen Knapp (b) (4)	31 Oct 2020 15:45:37

US3812085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:55:27

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	01 Feb 2021 20:39:27

US3812085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:55:27

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered '27 Jan 2021'	Breanna Galibert (b) (4)	01 Feb 2021 20:39:27

US3812085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:55:27

[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 12:04:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'Clinic (Clinic)'	Breanna Galibert (b) (4)	01 Feb 2021 20:39:27

**US3812085**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:55:27**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:40
User entered 'UNBLND_DECIDE'	System	01 Feb 2021 20:39:27

US3812085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:55:27

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered '27 Jan 2021'	Breanna Galibert (b) (4)	01 Feb 2021 20:39:39

US3812085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:55:27

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 12:04:40
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered '0'	Breanna Galibert (b) (4)	09 Mar 2021 16:11:04
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:26:37

US3812085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:55:27

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	01 Feb 2021 20:39:39



US3812085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:55:27

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:40
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'Amendment 6 or later (Amendment 6 or later)'	Breanna Galibert (b) (4)	09 Mar 2021 16:11:04
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 16:26:37

US3812085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:55:27

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered '27 Jan 2021'	Breanna Galibert (b) (4)	01 Feb 2021 20:39:39

US3812085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:55:27

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'mRNA-1273 (mRNA-1273)'	Breanna Galibert (b) (4)	01 Feb 2021 20:39:39

US3812085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:55:27

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'mRNA-1273 (mRNA-1273)'	Breanna Galibert (b) (4)	01 Feb 2021 20:39:39

US3812085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:55:27

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'mRNA-1273 (mRNA-1273)'	Breanna Galibert (b) (4)	01 Feb 2021 20:39:39

US3812085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:55:27

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'No (N)'	Breanna Galibert (b) (4)	01 Feb 2021 20:39:39

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:55:27

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:40
User entered empty.	System	01 Feb 2021 20:39:39

**US3812085**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:55:27**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:40
User entered empty.	System	01 Feb 2021 20:39:39



US3812085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	01 Feb 2021 20:39:52

US3812085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered '27 Jan 2021'	Breanna Galibert (b) (4)	01 Feb 2021 20:39:52

US3812085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:27

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered '17:20'	Breanna Galibert (b) (4)	01 Feb 2021 20:39:52

US3812085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:55:27

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:40
User entered '27 Jan 2021 17:20'	System	01 Feb 2021 20:39:52

US3812085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:55:27

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	01 Feb 2021 20:39:59

US3812085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:55:27

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered '27 Jan 2021'	Breanna Galibert (b) (4)	01 Feb 2021 20:39:59

US3812085

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:55:27

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:40
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered '17:25'	Breanna Galibert (b) (4)	01 Feb 2021 20:39:59

**US3812085**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:55:27**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:04:40
User entered '27 Jan 2021 17:25'	System	01 Feb 2021 20:39:59



US3812085

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:55:27

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:03
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:07:58
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'Yes (Y)' reason for change: New Information	Angie Kean (b) (4)	01 Dec 2020 21:19:50
User entered 'No (N)'	Karen Knapp (b) (4)	03 Sep 2020 13:12:23

US3812085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:43:53
User entered 'USA-US111-2021-mRNA-1273-P301000009'	System	29 Jan 2021 19:43:35
User entered 'New'	(b) (4), (b) (6)	29 Jan 2021 19:43:35

US3812085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Alopecias, PT: Alopecia areata, LLT: Alopecia areata - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	29 Jan 2021 01:18:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Jan 2021 01:18:09
Data point term sent to Coder	System	29 Jan 2021 01:17:47
User entered 'ALOPECIA AREATA' reason for change: Data Entry Error	Lyly Dang (b) (4)	29 Jan 2021 01:17:03
Data point term sent to Coder	System	28 Jan 2021 15:37:26
Coding entries removed.	Lyly Dang (b) (4)	28 Jan 2021 15:36:32
User entered 'Alopecia areata OF the BEARD' reason for change: Data Entry Error	Lyly Dang (b) (4)	28 Jan 2021 15:36:32
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Alopecias, PT: Alopecia, LLT: Hair thinning - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 10:21:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Dec 2020 10:21:10
Data point term sent to Coder	System	01 Dec 2020 21:26:29
User entered 'Thinning hair of beard'	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56

**US3812085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56

**US3812085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56

US3812085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered 'No (N)'	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56

US3812085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered '10 Sep 2020'	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56

US3812085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered empty.	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56



**US3812085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:27**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 21:25:56

**US3812085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered 'Yes (Y)'	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56

US3812085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 13:02:34
User entered empty.	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56

**US3812085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:27**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered empty.	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56

US3812085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' canceled (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 19:04:26
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time.?Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 19:04:08
User entered empty.	System	01 Dec 2020 21:25:56

**US3812085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered 'Grade 1/Mild (Grade 1/Mild)'	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56

US3812085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	29 Jan 2021 01:16:24
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	28 Jan 2021 15:36:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Lyly Dang (b) (4)	28 Jan 2021 15:36:32
User entered 'No (N)'	Angie Kean (b) (4)	01 Dec 2020 21:25:56

US3812085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered '0'	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56



US3812085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered '0'	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56

US3812085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered '0'	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56

US3812085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered empty.	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56

US3812085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered empty.	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56

**US3812085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered empty.	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered empty.	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56

US3812085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered '0'	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56

US3812085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered '0'	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered '1' reason for change: Data Entry Error	Lyly Dang (b) (4)	29 Jan 2021 01:16:24
User entered '0'	Angie Kean (b) (4)	01 Dec 2020 21:25:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered 'Related (RELATED)' reason for change: Data Entry Error	Lyly Dang (b) (4)	29 Jan 2021 01:16:49
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4)	01 Dec 2020 21:25:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered 'Not Related (NOT RELATED)'	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56

**US3812085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered 'Not Applicable (NOT APPLICABLE)'	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56

US3812085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:01:13
User closed query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	17 Mar 2021 21:42:42
DataPoint Un-verified.	Angie Kean (b) (4)	17 Mar 2021 21:42:42
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Angie Kean (b) (4)	17 Mar 2021 21:42:42
	(b) (4)	
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	17 Mar 2021 21:41:30
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:40:50
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' answered with 'conmed is being taken and will update' (Site from DM).	lauren clement (b) (4)	25 Feb 2021 20:45:54
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 02:22:56
User entered '1'	Angie Kean (b) (4)	01 Dec 2020 21:25:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if Descovy is a conmed and update the eCRF with details of conmed accordingly.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 15:29:15
Query 'PV Query: Please confirm if Descovy is a conmed and update the eCRF with details of conmed accordingly.' answered with 'medication listed in conmed log' (Site from Safety).	Angie Kean (b) (4)	29 Apr 2021 18:30:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 18:01:15
User closed query 'Per CDM: Please note there is a ConMed#3 associated with this condition. Please review "Other action taken" and reconcile data. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 14:30:38
Query 'Per CDM: Please note there is a ConMed#3 associated with this condition. Please review "Other action taken" and reconcile data. Thank you.' answered with 'updated' (Site from DM).	Angie Kean (b) (4)	17 Mar 2021 21:42:50
DataPoint Un-verified.	(b) (4)	
	Angie Kean (b) (4)	17 Mar 2021 21:41:30
User entered '1' reason for change: New Information	(b) (4)	17 Mar 2021 21:41:30
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
	(b) (4), (b) (6)	03 Mar 2021 19:05:23
User opened query 'PV Query: Please confirm if Descovy is a conmed and update the eCRF with details of conmed accordingly.' (Site from Safety).	(b) (4), (b) (6)	01 Mar 2021 08:40:49
User opened query 'Per CDM: Please note there is a ConMed#3 associated with this condition. Please review "Other action taken" and reconcile data. Thank you.' (Site from DM).		
User entered '0'	Angie Kean (b) (4)	01 Dec 2020 21:25:56
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered '0'	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 13:03:01
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User entered empty.	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56

US3812085

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:55:27

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:22:37
User closed query 'PV Query: Please provide a copy of the clinical note from the dermatologist with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 13:16:27
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 13:16:26
Query 'PV Query: Please provide a copy of the clinical note from the dermatologist with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342.' answered with 'Ok sending today' (Site from Safety).	lauren clement (b) (4)	25 Feb 2021 20:48:44
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'Subject seen and given betamethesone dipropionate 0.5% topical to affected area BID. Subject reports AE is the same and not resolving, but continues conmed' (Site from Safety).	lauren clement (b) (4)	25 Feb 2021 20:47:14
User opened query 'PV Query: Please provide a copy of the clinical note from the dermatologist with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 13:03:27

**US3812085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	09 Feb 2021 13:03:14
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	29 Jan 2021 01:16:24
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	29 Jan 2021 01:16:24
User entered 'Subject US3812085 reported at his clinic visit on Jan 27, 2021 that he was diagnosed with alopecia areata by his dermatologist on Dec 15, 2020. Subject initially reported "thinning beard" to site staff on October 26, 2020. The AE started on September 10, 2020 and was determined to be related to IP, as the subject received his second dose of IP on September 02, 2020. The subject denied having a family history of alopecia areata. As this condition is an autoimmune disorder, the AE was changed from not serious to serious. Medical records were requested on Jan 27, 2021.' reason for change: Data Entry Error	Lyly Dang (b) (4)	29 Jan 2021 01:16:24
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	28 Jan 2021 15:36:32
User entered empty.	Angie Kean (b) (4) (b) (4)	01 Dec 2020 21:25:56

**US3812085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Jan 2021 15:36:32
User entered '0'	System	01 Dec 2020 21:25:56

**US3812085**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Dec 2020 21:25:56

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:55:27

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 20:11:03
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:17:04
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2 and Day 3 (03SEP2020-04SEP2020), 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)	01 Mar 2021 10:21:53
Query 'Per DM CLR: Per Diary Dose 2 Day 2 and Day 3 (03SEP2020-04SEP2020), 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 'reconciled' (Site from DM).	lauren clement (b) (4)	24 Feb 2021 17:40:47
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2 and Day 3 (03SEP2020-04SEP2020), 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 07:34:33
User entered 'Yes (Y)'	Breanna Galibert (b) (4) (b) (4)	10 Aug 2020 18:25:43

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:27

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: EMTRICITABINE;TENOFVIR DISOPROXIL FUMARATE, PRODUCTSYNONYM: TRUVADA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 18:27:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	10 Aug 2020 18:27:22
Data point term sent to Coder	System	10 Aug 2020 18:26:33
User entered 'TRUVADA'	Breanna Galibert (b) (4)	10 Aug 2020 18:26:21

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:27

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 18:26:21



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:27

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'HIV PREVENTATIVE'	Breanna Galibert (b) (4)	10 Aug 2020 18:26:21

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:27

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'I'	Breanna Galibert (b) (4)	10 Aug 2020 18:26:21

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:27

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'tablet (TABLET)'	Breanna Galibert (b) (4)	10 Aug 2020 18:26:21

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:27

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 18:26:21

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:27

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'once daily (QD)'	Breanna Galibert (b) (4)	10 Aug 2020 18:26:21

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:27

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 18:26:21

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:27

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	10 Aug 2020 18:26:21

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:27

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 18:26:21



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	12 Aug 2020 14:42:41
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	10 Aug 2020 18:26:21
User entered 'UN May 2019'	Breanna Galibert (b) (4) (b) (4)	10 Aug 2020 18:26:21

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered '0'	Breanna Galibert (b) (4)	10 Aug 2020 18:26:21

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:27

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Signature has been broken.	Breanna Galibert (b) (4)	23 Mar 2021 13:40:34
User entered 'No (N)' reason for change: New Information	Breanna Galibert (b) (4)	23 Mar 2021 13:40:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	10 Aug 2020 18:26:21

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Signature has been broken.	Breanna Galibert (b) (4)	23 Mar 2021 13:40:34
User entered '01 Oct 2020' reason for change: New Information	Breanna Galibert (b) (4)	23 Mar 2021 13:40:34
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered empty.	Breanna Galibert (b) (4)	10 Aug 2020 18:26:21

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:55:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'No (N)'	Breanna Galibert (b) (4)	10 Aug 2020 18:26:21

**US3812085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 18:26:21

**US3812085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	10 Aug 2020 18:26:21

**US3812085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	10 Aug 2020 18:26:21



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:27

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 17:42:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Feb 2021 17:42:59
Data point term sent to Coder User entered 'Ibuprofen'	System lauren clement (b) (4)	24 Feb 2021 17:41:58 24 Feb 2021 17:41:46

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:27

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'No (N)'	lauren clement (b) (4)	24 Feb 2021 17:41:46

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:27

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 14:29:45
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'solicited event, does not meet criteria for ae' (Site from DM).	Angie Kean (b) (4) (b) (4)	17 Mar 2021 21:40:12

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:27

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM). User entered 'Headache'	(b) (4), (b) (6) (b) (4) (b) (4)	15 Mar 2021 09:31:52
	lauren clement (b) (4) (b) (4) (b) (4)	24 Feb 2021 17:41:46

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:27

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered '200'	lauren clement (b) (4)	24 Feb 2021 17:41:46

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:27

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'mg (mg)'	lauren clement (b) (4)	24 Feb 2021 17:41:46

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:27

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered empty.	lauren clement (b) (4)	24 Feb 2021 17:41:46

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:27

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'once daily (QD)'	lauren clement (b) (4)	24 Feb 2021 17:41:46



US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered empty.	lauren clement (b) (4)	24 Feb 2021 17:41:46

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:27

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'Oral (ORAL)'	lauren clement (b) (4)	24 Feb 2021 17:41:46

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:27

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered empty.	lauren clement (b) (4)	24 Feb 2021 17:41:46

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered '03 Sep 2020'	lauren clement (b) (4)	24 Feb 2021 17:41:46

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered '0'	lauren clement (b) (4)	24 Feb 2021 17:41:46

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:27

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'No (N)'	lauren clement (b) (4)	24 Feb 2021 17:41:46

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered '04 Sep 2020'	lauren clement (b) (4)	24 Feb 2021 17:41:46

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:55:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'Yes (Y)'	lauren clement (b) (4)	24 Feb 2021 17:41:46



**US3812085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:55:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Feb 2021 17:41:46

**US3812085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:55:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	24 Feb 2021 17:41:46

**US3812085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:55:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Feb 2021 17:41:46

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:27

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, POTENT (GROUP III), PRODUCT: BETAMETHASONE DIPROPIONATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 23:43:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 23:43:53
Data point term sent to Coder	System	25 Feb 2021 20:51:00
User entered 'BETAMETHESONE DIPROPIONATE 0.5%'	lauren clement (b) (4)	25 Feb 2021 20:50:30

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:27

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'No (N)'	lauren clement (b) (4)	25 Feb 2021 20:50:30

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:27

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'ALOPECIA AREATA'	lauren clement (b) (4)	25 Feb 2021 20:50:30

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:27

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User closed query 'Per CDM: "Dose per administration" = "1 APPLICATION" and "Dose unit" = "%". Please update the dose unit to "Application" and leave the "Dose per administration" = "1". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 14:30:10
Query 'Per CDM: "Dose per administration" = "1 APPLICATION" and "Dose unit" = "%". Please update the dose unit to "Application" and leave the "Dose per administration" = "1". Please review and reconcile. Thank you. ' answered with 'updated' (Site from DM).	Angie Kean (b) (4) (b) (4)	17 Mar 2021 21:40:45
User entered '1' reason for change: Data Entry Error	Angie Kean (b) (4) (b) (4)	17 Mar 2021 21:40:38
User opened query 'Per CDM: "Dose per administration" = "1 APPLICATION" and "Dose unit" = "%". Please update the dose unit to "Application" and leave the "Dose per administration" = "1". Please review and reconcile. Thank you. ' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 10:07:54
User entered '1 APPLICATION'	lauren clement (b) (4)	25 Feb 2021 20:50:30

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:27

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'Other (OTHER)'	lauren clement (b) (4)	25 Feb 2021 20:50:30



US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:27

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'application' reason for change: New Information	Angie Kean (b) (4)	17 Mar 2021 21:40:38
User entered '0.5%'	lauren clement (b) (4)	25 Feb 2021 20:50:30

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:27

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'twice daily (BID)'	lauren clement (b) (4)	25 Feb 2021 20:50:30

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:27

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered empty.	lauren clement (b) (4)	25 Feb 2021 20:50:30

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:27

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'Topical (TOPICAL)'	lauren clement (b) (4)	25 Feb 2021 20:50:30

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:27

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered empty.	lauren clement (b) (4)	25 Feb 2021 20:50:30

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered '15 Dec 2020'	lauren clement (b) (4)	25 Feb 2021 20:50:30

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered '0'	lauren clement (b) (4)	25 Feb 2021 20:50:30

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:27

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'Yes (Y)'	lauren clement (b) (4)	25 Feb 2021 20:50:30



US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered empty.	lauren clement (b) (4)	25 Feb 2021 20:50:30

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:55:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'No (N)'	lauren clement (b) (4)	25 Feb 2021 20:50:30

**US3812085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:55:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	25 Feb 2021 20:50:30

**US3812085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:55:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	25 Feb 2021 20:50:30

**US3812085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:55:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Feb 2021 20:50:30

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:27

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: ANTIVIRALS FOR TREATMENT OF HIV INFECTIONS, COMBINATIONS, PRODUCT: EMTRICITABINE;TENOFOVIR ALAFENAMIDE FUMARATE, PRODUCTSYNONYM: DESCOVY - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 00:56:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Mar 2021 00:56:23
User signature succeeded.	Lyly Dang (b) (4) (b) (4)	26 Mar 2021 19:46:16
Data point term sent to Coder	System	23 Mar 2021 13:41:58
User entered 'emtricitabine 200 mg/descovy tenefovir alatenamide 25 mg'	Breanna Galibert (b) (4) (b) (4)	23 Mar 2021 13:41:42

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:27

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	23 Mar 2021 13:41:42

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:27

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'hiv preventative'	Breanna Galibert (b) (4)	23 Mar 2021 13:41:42



US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:27

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'I'	Breanna Galibert (b) (4)	23 Mar 2021 13:41:42

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:27

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'tablet (TABLET)'	Breanna Galibert (b) (4)	23 Mar 2021 13:41:42

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:27

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 13:41:42

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:27

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'once daily (QD)'	Breanna Galibert (b) (4)	23 Mar 2021 13:41:42

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:27

If frequency is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 13:41:42

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:27

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	23 Mar 2021 13:41:42

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:27

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 13:41:42

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered '02 Oct 2020'	Breanna Galibert (b) (4)	23 Mar 2021 13:41:42



US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered '0'	Breanna Galibert (b) (4)	23 Mar 2021 13:41:42

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:27

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	23 Mar 2021 13:41:42

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered empty.	Breanna Galibert (b) (4)	23 Mar 2021 13:41:42

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:55:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'No (N)'	Breanna Galibert (b) (4)	23 Mar 2021 13:41:42

**US3812085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:55:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 13:41:42

US3812085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:55:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Mar 2021 13:41:42

**US3812085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:55:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Mar 2021 13:41:42

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:27

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: ACICLOVIR, PRODUCTSYNONYM: ACYCLOVIR [ACICLOVIR] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 08:23:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Mar 2021 08:23:51
Data point term sent to Coder	System	24 Mar 2021 16:35:33
User entered 'acyclovir'	Breanna Galibert (b) (4)	24 Mar 2021 16:35:32



US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:27

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'No (N)'	Breanna Galibert (b) (4)	24 Mar 2021 16:35:32

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:27

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'Herpes simplex virus TYPE 2'	Breanna Galibert (b) (4)	24 Mar 2021 16:35:32

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:27

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'I'	Breanna Galibert (b) (4)	24 Mar 2021 16:35:32

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:27

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'g (g)'	Breanna Galibert (b) (4)	24 Mar 2021 16:35:32

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:27

If dose unit is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered empty.	Breanna Galibert (b) (4)	24 Mar 2021 16:35:32

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:27

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'as needed (PRN)'	Breanna Galibert (b) (4)	24 Mar 2021 16:35:32

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:27

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered empty.	Breanna Galibert (b) (4)	24 Mar 2021 16:35:32

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:27

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'Oral (ORAL)'	Breanna Galibert (b) (4)	24 Mar 2021 16:35:32



US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:27

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered empty.	Breanna Galibert (b) (4)	24 Mar 2021 16:35:32

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:27

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'UN Apr 2020'	Breanna Galibert (b) (4)	24 Mar 2021 16:35:32

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:27

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered '0'	Breanna Galibert (b) (4)	24 Mar 2021 16:35:32

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:27

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'Yes (Y)'	Breanna Galibert (b) (4)	24 Mar 2021 16:35:32

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:27

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered empty.	Breanna Galibert (b) (4)	24 Mar 2021 16:35:32

US3812085

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:55:27

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:18:00
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered 'No (N)'	Breanna Galibert (b) (4)	24 Mar 2021 16:35:32

**US3812085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:55:27**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 16:35:32

**US3812085**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:55:27**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 16:35:32



US3812085

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:55:27**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Mar 2021 16:35:32

US3812085

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 10 Jun 2021 09:55:27**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
	(b) (4)	
User entered 'No (N)'	Karen Knapp (b) (4)	03 Sep 2020 13:12:18
	(b) (4)	

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'USA-US111-2021-MRNA-1273-P301000009'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'Yes (Y)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35



US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'Yes (Y)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered 'lauren'	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'Larkin'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered 'clement'	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'Wadsworth'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered empty.	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered '711 Old Ballas Rd Suite 105'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered empty.	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'St Louis'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
User entered 'MO'	System	18 Mar 2021 17:22:15

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered empty.	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered '63141'	System	29 Jan 2021 19:43:35



**US3812085**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:27**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 15:36:15
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'US'	(b) (4) System	29 Jan 2021 19:44:13

**US3812085**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:27**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 14:56:31
User entered '3'	System	18 Mar 2021 17:22:15
Signature has been broken.	System	26 Feb 2021 15:36:36
User entered '2'	System	26 Feb 2021 15:36:36
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
	(b) (4)	
User entered '1'	System	29 Jan 2021 19:44:13

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'USA-US111-2021-MRNA-1273-P301000009'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'Yes (Y)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35



US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'Yes (Y)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered 'lauren'	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'Larkin'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered 'clement'	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'Wadsworth'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered empty.	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered '711 Old Ballas Rd Suite 105'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered empty.	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'St Louis'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
User entered 'MO'	System	18 Mar 2021 17:22:15

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered empty.	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered '63141'	System	29 Jan 2021 19:43:35



**US3812085**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:27**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 15:36:15
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'US'	(b) (4) System	29 Jan 2021 19:44:13

**US3812085**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:27**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 14:56:31
User entered '3'	System	18 Mar 2021 17:22:15
Signature has been broken.	System	26 Feb 2021 15:36:36
User entered '2'	System	26 Feb 2021 15:36:36
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
	(b) (4)	
User entered '1'	System	29 Jan 2021 19:44:13

**US3812085**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000009**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:55:27**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered '29/Jan/2021 14:44'	(b) (4) System	29 Jan 2021 19:44:13

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:55:27

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 15:36:15
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:13

**US3812085**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:27**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'USA-US111-2021-MRNA-1273-P301000009'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'Yes (Y)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35



US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'Yes (Y)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered 'lauren'	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'Larkin'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered 'clement'	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'Wadsworth'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered empty.	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered '711 Old Ballas Rd Suite 105'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered empty.	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'St Louis'	System	29 Jan 2021 19:43:35



**US3812085**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:27**

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
User entered 'MO'	System	18 Mar 2021 17:22:15

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered empty.	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered '63141'	System	29 Jan 2021 19:43:35

**US3812085**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:27**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 15:36:15
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'US'	(b) (4) System	29 Jan 2021 19:44:13

**US3812085**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:27**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 14:56:31
User entered '3'	System	18 Mar 2021 17:22:15
Signature has been broken.	System	26 Feb 2021 15:36:36
User entered '2'	System	26 Feb 2021 15:36:36
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
	(b) (4)	
User entered '1'	System	29 Jan 2021 19:44:13

**US3812085**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000009**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:55:27**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User entered '26/Feb/2021 09:36'	System	26 Feb 2021 15:36:36

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:55:27

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User entered 'I'	(b) (4), (b) (6)	26 Feb 2021 15:36:36

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'USA-US111-2021-MRNA-1273-P301000009'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'Yes (Y)'	System	29 Jan 2021 19:43:35



US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'Yes (Y)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered 'lauren'	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'Larkin'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered 'clement'	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'Wadsworth'	System	29 Jan 2021 19:43:35



US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered empty.	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered '711 Old Ballas Rd Suite 105'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered empty.	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'St Louis'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
User entered 'MO'	System	18 Mar 2021 17:22:15

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered empty.	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered '63141'	System	29 Jan 2021 19:43:35

**US3812085**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:27**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 15:36:15
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'US'	(b) (4) System	29 Jan 2021 19:44:13

**US3812085**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:27**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 14:56:31
User entered '3'	System	18 Mar 2021 17:22:15
Signature has been broken.	System	26 Feb 2021 15:36:36
User entered '2'	System	26 Feb 2021 15:36:36
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
	(b) (4)	
User entered '1'	System	29 Jan 2021 19:44:13

**US3812085**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000009**

**Form: Safety Report Form (3)**

**Generated On: 10 Jun 2021 09:55:27**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
User entered '18/Mar/2021 13:22'	System	18 Mar 2021 17:22:15

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 10 Jun 2021 09:55:27

**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.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
User entered 'I'	(b) (4), (b) (6)	18 Mar 2021 17:22:15



US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'USA-US111-2021-MRNA-1273-P301000009'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'Yes (Y)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'No (N)'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'Yes (Y)'	System	29 Jan 2021 19:43:35



US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered 'lauren'	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'Larkin'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered 'clement'	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'Wadsworth'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered empty.	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered '711 Old Ballas Rd Suite 105'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered empty.	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered 'St Louis'	System	29 Jan 2021 19:43:35

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
User entered 'MO'	System	18 Mar 2021 17:22:15

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:55:27

Site Address: Postal Code

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:00:29
User signature succeeded.	Lyly Dang (b) (4)	26 Mar 2021 19:46:16
Reviewed for Safety.	(b) (4), (b) (6)	18 Mar 2021 17:22:27
Un-reviewed for Safety.	System	18 Mar 2021 17:22:15
DataPoint Un-verified.	System	18 Mar 2021 17:22:15
Signature has been broken.	System	18 Mar 2021 17:22:15
User entered empty.	System	18 Mar 2021 17:22:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
Reviewed for Safety.	(b) (4), (b) (6)	29 Jan 2021 19:44:06
User entered '63141'	System	29 Jan 2021 19:43:35

**US3812085**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:27**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 22:06:49
Reviewed for Safety.	(b) (4), (b) (6)	26 Feb 2021 15:36:15
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
User entered 'US'	(b) (4) System	29 Jan 2021 19:44:13

**US3812085**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:55:27**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	30 Apr 2021 14:56:31
User entered '3'	System	18 Mar 2021 17:22:15
Signature has been broken.	System	26 Feb 2021 15:36:36
User entered '2'	System	26 Feb 2021 15:36:36
User signature succeeded.	Larkin Wadsworth (b) (4)	20 Feb 2021 19:39:26
	(b) (4)	
User entered '1'	System	29 Jan 2021 19:44:13



**US3812085**

**Folder: SAE USA-US111-2021-MRNA-1273-P301000009**

**Form: Safety Report Form (4)**

**Generated On: 10 Jun 2021 09:55:27**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	01 May 2021 20:47:48
User entered '30/Apr/2021 10:56'	System	30 Apr 2021 14:56:31

US3812085

Folder: SAE USA-US111-2021-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 10 Jun 2021 09:55:27

**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.**

Audit	User	Time (GMT)
User signature succeeded.	Lyly Dang (b) (4)	01 May 2021 20:47:48
User entered 'I'	(b) (4), (b) (6)	30 Apr 2021 14:56:31