

US3782198 (Prod: Vanderbilt University Medical Center)

Generated By: KC Joubran

Generated On: 12 Aug 2021 13:33:17

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US3782198

Form: Participant Creation

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

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Participant ID

US3782198

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

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US3782198

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:33:36

Generated On: 12 Aug 2021 13:33:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Jan 2021 20:33:36

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Date of Birth (MMM yyyy)	(b) (6) 1990
Age	30
Age Units	YEARS
Age (Derived)	30
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Jan 2021 20:33:36

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	23 OCT 2020
Month and Year of Informed Consent (derived)	OCT 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input type="radio"/> Amendment 4 <input checked="" 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) 26 Jan 2021 20:33:36

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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) 26 Jan 2021 20:33:36

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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 Jan 2021 20:33:36

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Condition	OCCASIONAL BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2006
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2006
Start Year (derived)	2006
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Jan 2021 20:33:36

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Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2008
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2008
Start Year (derived)	2008
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Jan 2021 20:33:36

Generated On: 12 Aug 2021 13:33:17

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

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Jan 2021 20:33:36

Generated On: 12 Aug 2021 13:33:17

Condition	STREP PHARYNGITIS
Start date (dd MMM yyyy)	17 OCT 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)	OCT 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) 26 Jan 2021 20:33:36

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	23 OCT 2020
Time of assessment (00:00-23:59)	12:48 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 12:48
Height (xxx.x)	181 cm
Weight (xxx.x)	72.1 kg
BMI (xxx.x)	22.00788 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:33:36

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 OCT 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) 26 Jan 2021 20:33:36

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**Occupational Risk**

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

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

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

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

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

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

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

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

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

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

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

**Other** Yes ☐ No ☒

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**Specify**

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

**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Jan 2021 20:33:36

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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)	True
<b>Resides in low density, multi-family setting without</b> (e.g., apartments complex without shared entrances or elevators, duplexes)	False
<b>Resides in a single family home</b> (i.e., detached housing)	False
<b>Other</b>	False
<b>Specify</b>	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:33:36

Generated On: 12 Aug 2021 13:33:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1



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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Jan 2021 20:33:36

Generated On: 12 Aug 2021 13:33:17

What was the date of randomization? (dd MMM yyyy) 23 OCT 2020

What was the participant's randomization number? 117670

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Jan 2021 20:33:36

Generated On: 12 Aug 2021 13:33:17

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) 26 Jan 2021 20:33:36

Generated On: 12 Aug 2021 13:33:17

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)	23 OCT 2020
Time of assessment (00:00-23:59)	12:48 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 12:48
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Jan 2021 20:33:36

Generated On: 12 Aug 2021 13:33:17

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)	23 OCT 2020
Time of assessment (00:00-23:59)	13:59 (24 HR)
Vital Signs Date and Time (derived)	23 OCT 2020 13:59
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)	100 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)	82 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:33:36

Generated On: 12 Aug 2021 13:33:17

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) 26 Jan 2021 20:33:36

Generated On: 12 Aug 2021 13:33:17

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) 23 OCT 2020

What was the treatment time? (00:00-23:59) 13:29 (24 HR)

Treatment Date and Time (derived) 23 OCT 2020 13:29

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) 26 Jan 2021 20:33:36

Generated On: 12 Aug 2021 13:33:17

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 OCT 2020

Collection time (00:00-23:59)

12:56 (24 HR)

Collection date and time (derived)

23 OCT 2020 12:56

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Jan 2021 20:33:36

Generated On: 12 Aug 2021 13:33:17

Collection date (dd MMM yyyy)			23 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:58	23 OCT 2020 12:58
Nasopharyngeal Swab 2	No		



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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:33:36

Generated On: 12 Aug 2021 13:33:17

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: 12 Aug 2021 13:33:17

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 OCT 2020 14:04

PC Open Date & Time

23 OCT 2020 13:49

PC Close Date & Time

23 OCT 2020 16:19

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

PC Time Stamp	23 OCT 2020 19:23
PC Open Date & Time	23 OCT 2020 17:14
PC Close Date & Time	24 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:33:17

**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

98.5 °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

24 OCT 2020 17:14

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:33:17

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**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

98.5 °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

26 OCT 2020 08:15

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:33:17

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**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 OCT 2020 19:01

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:33:17

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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.

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.9 °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

27 OCT 2020 17:54

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:33:17

---

**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

98.5 °F

---

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

Yes ☐

No ☒

---

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

---

PC Time Stamp

28 OCT 2020 17:31

---

PC Open Date & Time

28 OCT 2020 12:00

---

PC Close Date & Time

29 OCT 2020 11:59

---



US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.1 °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

29 OCT 2020 16:45

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

**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

23 OCT 2020 14:04

PC Open Date & Time

23 OCT 2020 13:49

PC Close Date & Time

23 OCT 2020 16:19

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

**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

23 OCT 2020 19:23

PC Open Date & Time

23 OCT 2020 17:14

PC Close Date & Time

24 OCT 2020 11:59

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:33:17

**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

24 OCT 2020 17:15

PC Open Date & Time

24 OCT 2020 12:00

PC Close Date & Time

25 OCT 2020 11:59

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:33:17

**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

26 OCT 2020 08:15

PC Open Date & Time

25 OCT 2020 12:00

PC Close Date & Time

26 OCT 2020 11:59

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:33:17

**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

26 OCT 2020 19:01

PC Open Date & Time

26 OCT 2020 12:00

PC Close Date & Time

27 OCT 2020 11:59

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:33:17

**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

27 OCT 2020 17:54

PC Open Date & Time

27 OCT 2020 12:00

PC Close Date & Time

28 OCT 2020 11:59

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:33:17

**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

28 OCT 2020 17:31

PC Open Date & Time

28 OCT 2020 12:00

PC Close Date & Time

29 OCT 2020 11:59



US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:33:17

**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

29 OCT 2020 16:45

PC Open Date & Time

29 OCT 2020 12:00

PC Close Date & Time

30 OCT 2020 11:59

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

**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 ☐

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

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

No ☒

Yes ☐

PC Time stamp	23 OCT 2020 14:05
PC Open Date & Time	23 OCT 2020 13:49
PC Close Date & Time	23 OCT 2020 16:19

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

**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 ☐

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

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

No ☒

Yes ☐

PC Time stamp	23 OCT 2020 19:24
PC Open Date & Time	23 OCT 2020 17:14
PC Close Date & Time	24 OCT 2020 11:59

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:33:17

**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 ☒

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:33:17

Yes <input type="checkbox"/>	
PC Time stamp	24 OCT 2020 17:15
PC Open Date & Time	24 OCT 2020 12:00
PC Close Date & Time	25 OCT 2020 11:59

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:33:17

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

47 of 1572

EAB) (1725)



US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:33:17

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 08:16
PC Open Date & Time	25 OCT 2020 12:00
PC Close Date & Time	26 OCT 2020 11:59

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:17

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

49 of 1572

EAB) (1725)

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:17

Yes <input type="checkbox"/>	
PC Time stamp	26 OCT 2020 19:01
PC Open Date & Time	26 OCT 2020 12:00
PC Close Date & Time	27 OCT 2020 11:59

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:17

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

51 of 1572

EAB) (1725)

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:17

Yes <input type="checkbox"/>	
PC Time stamp	27 OCT 2020 17:54
PC Open Date & Time	27 OCT 2020 12:00
PC Close Date & Time	28 OCT 2020 11:59

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:17

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 1572

EAB) (1725)

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:17

Yes <input type="checkbox"/>	
PC Time stamp	28 OCT 2020 17:31
PC Open Date & Time	28 OCT 2020 12:00
PC Close Date & Time	29 OCT 2020 11:59

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:17

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 ☒



US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:17

Yes <input type="checkbox"/>	
PC Time stamp	29 OCT 2020 16:45
PC Open Date & Time	29 OCT 2020 12:00
PC Close Date & Time	30 OCT 2020 11:59

US3782198

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

DAY 8

Select one response below to indicate the intensity of your

None ☒

**HEADACHE**

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 ☐

PC Time Stamp 31 OCT 2020 08:13

PC Open Date & Time 30 OCT 2020 12:00

PC Close Date & Time 31 OCT 2020 11:59

US3782198

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 12 Aug 2021 13:33:17

<b>TIMEPOINT</b>	DAY 8
Did you receive any <b>MEDICAL ATTENTION</b> (doctor visit, <b>other</b> ) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	31 OCT 2020 08:13
PC Open Date & Time	30 OCT 2020 12:00
PC Close Date & Time	31 OCT 2020 11:59

US3782198

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782198

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782198

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782198

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782198

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3782198

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782198

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:33:39

Generated On: 12 Aug 2021 13:33:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	27 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Jan 2021 20:33:39

Generated On: 12 Aug 2021 13:33:17

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)	27 NOV 2020
Time of assessment (00:00-23:59)	11:20 (24 HR)
Vital Signs Date and Time (derived)	27 NOV 2020 11:20
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)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Jan 2021 20:33:39

Generated On: 12 Aug 2021 13:33:17

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input checked="" type="checkbox"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3782198

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:33:36

Generated On: 12 Aug 2021 13:33:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 NOV 2020

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

US3782198

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Jan 2021 20:33:36

Generated On: 12 Aug 2021 13:33:17

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

NEW ONSET RASH OF UNKNOWN ETIOLOGY

What was the study treatment? \_\_\_\_\_

What was the treatment date? (dd MMM yyyy) \_\_\_\_\_

What was the treatment time? (00:00-23:59) \_\_\_\_\_

Treatment Date and Time (derived) \_\_\_\_\_

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

What was the frequency of the study treatment dosing? \_\_\_\_\_

What was the route of administration for the study treatment? \_\_\_\_\_

US3782198

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:33:36

Generated On: 12 Aug 2021 13:33:17

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

27 NOV 2020

Collection time (00:00-23:59)

11:12 (24 HR)

Collection date and time (derived)

27 NOV 2020 11:12

US3782198

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Jan 2021 20:33:36

Generated On: 12 Aug 2021 13:33:17

Collection date (dd MMM yyyy)			27 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:15	27 NOV 2020 11:15
Nasopharyngeal Swab 2	No		



US3782198

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:33:36

Generated On: 12 Aug 2021 13:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782198

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782198

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782198

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782198

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782198

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782198

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782198

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:33:39

Generated On: 12 Aug 2021 13:33:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 DEC 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



US3782198

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Jan 2021 20:33:39

Generated On: 12 Aug 2021 13:33:17

Were vital signs assessed? Yes ☐  
No ☒

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

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

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

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

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

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

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

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

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

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

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

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

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

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

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

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

US3782198

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:33:39

Generated On: 12 Aug 2021 13:33:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 DEC 2020

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

US3782198

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:33:39

Generated On: 12 Aug 2021 13:33:17

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 DEC 2020

Collection time (00:00-23:59)

10:15 (24 HR)

Collection date and time (derived)

23 DEC 2020 10:15

US3782198

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:33:39

Generated On: 12 Aug 2021 13:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

TIMEPOINT	DAY 61
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 DEC 2020 10:27:29
Patient Cloud Open Date & Time	20 DEC 2020 00:01
Patient Cloud Close Date & Time	24 DEC 2020 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

TIMEPOINT	DAY 68
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 DEC 2020 00:02:46
Patient Cloud Open Date & Time	27 DEC 2020 00:01
Patient Cloud Close Date & Time	31 DEC 2020 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

TIMEPOINT	DAY 75
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 JAN 2021 00:08:17
Patient Cloud Open Date & Time	03 JAN 2021 00:01
Patient Cloud Close Date & Time	07 JAN 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

TIMEPOINT	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 JAN 2021 08:52:40
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59



US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

<b>TIMEPOINT</b>	DAY 89
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 JAN 2021 12:00:30
Patient Cloud Open Date & Time	17 JAN 2021 00:01
Patient Cloud Close Date & Time	21 JAN 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 JAN 2021 00:08:20
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 00:01:22

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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

10 FEB 2021 11:40:16

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	18 FEB 2021 18:49:35
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 FEB 2021 12:00:22
Patient Cloud Open Date & Time	21 FEB 2021 00:01
Patient Cloud Close Date & Time	25 FEB 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	03 MAR 2021 13:21:58
Patient Cloud Open Date & Time	28 FEB 2021 00:01
Patient Cloud Close Date & Time	04 MAR 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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

07 MAR 2021 00:01:45

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59



US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 MAR 2021 00:02:29
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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

21 MAR 2021 00:02:16

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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

31 MAR 2021 09:53:21

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

<b>TIMEPOINT</b>	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 APR 2021 12:00:57
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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

11 APR 2021 00:08:51

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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

19 APR 2021 01:46:37

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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

25 APR 2021 00:03:26

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

02 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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09 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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13 MAY 2021 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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 <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"/>

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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30 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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03 JUN 2021 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

13 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Close Date & Time](#)

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24 JUN 2021 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

DAY 257

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Close Date & Time](#)

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08 JUL 2021 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

11 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUL 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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18 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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22 JUL 2021 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

DAY 285

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

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

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

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

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

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

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

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	15 AUG 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	19 AUG 2021 23:59
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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Close Date & Time](#)

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09 SEP 2021 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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"/>



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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23 SEP 2021 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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"/>

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

26 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Close Date & Time](#)

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07 OCT 2021 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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31 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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07 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 NOV 2021 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	14 NOV 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	18 NOV 2021 23:59
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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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21 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 NOV 2021 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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"/>

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

05 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

09 DEC 2021 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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°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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Close Date & Time](#)

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06 JAN 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Close Date & Time](#)

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13 JAN 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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20 JAN 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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"/>

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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23 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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30 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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"/>

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 FEB 2022 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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"/>

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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°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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Close Date & Time](#)

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31 MAR 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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

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 ☐



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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03 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 APR 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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10 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 APR 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Close Date & Time](#)

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21 APR 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

[Patient Cloud Close Date & Time](#)

28 APR 2022 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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01 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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05 MAY 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Close Date & Time](#)

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12 MAY 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

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

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

DAY 579

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

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

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

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

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

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

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

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

DAY 586

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

DAY 593

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

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

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

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

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

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

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

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

05 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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"/>

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Close Date & Time](#)

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23 JUN 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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"/>



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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"/>

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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03 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUL 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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10 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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14 JUL 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 JUL 2022 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Close Date & Time](#)

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28 JUL 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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°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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Close Date & Time](#)

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18 AUG 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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"/>



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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°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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐ Yes ☐

Have you been exposed to someone with known SARS-CoV-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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Close Date & Time](#)

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08 SEP 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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"/>

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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18 SEP 2022 00:01

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[Patient Cloud Close Date & Time](#)

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22 SEP 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	25 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2022 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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 <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"/>

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Close Date & Time](#)

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06 OCT 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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"/>

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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"/>



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Close Date & Time](#)

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20 OCT 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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"/>

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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23 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 OCT 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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"/>

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

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30 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

[Patient Cloud Close Date & Time](#)

10 NOV 2022 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 NOV 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 NOV 2022 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2022 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2022 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Close Date & Time](#)

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01 DEC 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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°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 ☐

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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[Patient Cloud Open Date & Time](#)

04 DEC 2022 00:01

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[Patient Cloud Close Date & Time](#)

08 DEC 2022 23:59

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US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

**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°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 ☐



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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 <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"/>

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 DEC 2022 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2022 23:59

US3782198

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 12 Aug 2021 13:33:17

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"/>

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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 DEC 2022 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2022 23:59
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US3782198

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 12 Aug 2021 13:33:17

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
Yes	No	03 MAR 2021 13:22:11

US3782198

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782198

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3782198

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 01:23:35

Generated On: 12 Aug 2021 13:33:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782198

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 01:23:35

Generated On: 12 Aug 2021 13:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782198

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 01:23:35

Generated On: 12 Aug 2021 13:33:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

24 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782198

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 01:23:35

Generated On: 12 Aug 2021 13:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782198

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:43:33

Generated On: 12 Aug 2021 13:33:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782198

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:43:33

Generated On: 12 Aug 2021 13:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3782198**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:33:17**

Was this visit performed? Yes ☐  
No ☐

Visit date (dd MMM yyyy) \_\_\_\_\_

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

Folder OID \_\_\_\_\_

US3782198

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

Were vital signs assessed?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment ( <i>dd MMM yyyy</i> )	
Time of assessment ( <i>00:00-23:59</i> )	
Vital Signs Date and Time (derived)	
Temperature ( <i>xxx.x</i> )	
Route of measurement	Oral <input type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse ( <i>xxx</i> )	
Pulse units	
Respiratory Rate ( <i>xxx</i> )	
Respiratory Rate units	
Systolic Blood Pressure ( <i>xxx</i> )	
Systolic Blood Pressure units	
Diastolic Blood Pressure ( <i>xxx</i> )	
Diastolic Blood Pressure units	
Height (derived)	
Weight (derived)	



US3782198

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:17

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.*

US3782198

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:17

Was the sample collected?

Yes ☐

No ☐

Collection date (*dd MMM yyyy*)

Collection time (*00:00-23:59*)

Collection date and time (derived)

**US3782198**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:33:17**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3782198

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

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

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

Visit date (dd MMM yyyy)	18 JAN 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3782198

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 01:23:35

Generated On: 12 Aug 2021 13:33:17

Date of updated informed consent ( <i>dd MMM yyyy</i> )	18 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding ( <i>dd MMM yyyy</i> )	18 JAN 2021
Participant randomization assignment	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/>
Actual Dose 1	mRNA-1273 <input checked="" type="radio"/> Placebo <input type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input type="radio"/> Not Administered <input checked="" type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	
Continuing with mRNA-1273	1

US3782198

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

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

US3782198

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 JAN 2021
Time of assessment (00:00-23:59)	14:18 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 14:18
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	92 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	113 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3782198

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	18 JAN 2021
Time of assessment (00:00-23:59)	14:59 (24 HR)
Vital Signs Date and Time (derived)	18 JAN 2021 14:59
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)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	77 mmHg
Diastolic Blood Pressure units	MMHG



US3782198

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

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

18 JAN 2021

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

US3782198

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

Form: Exposure

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? (Unblinded) MRNA-1273

What was the treatment date? (dd MMM yyyy) 18 JAN 2021

What was the treatment time? (00:00-23:59) 14:29 (24 HR)

Treatment Date and Time (derived) 18 JAN 2021 14:29

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

US3782198

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 JAN 2021

Collection time (00:00-23:59)

14:10 (24 HR)

Collection date and time (derived)

18 JAN 2021 14:10

US3782198

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 JAN 2021

Collection time (00:00 - 23:59)

14:12

Collection Date and Time (derived)

18 JAN 2021 14:12

US3782198

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

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782198

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:33:36

Generated On: 12 Aug 2021 13:33:17

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782198

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:33:36

Generated On: 12 Aug 2021 13:33:17

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3782198

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 01:23:35

Generated On: 12 Aug 2021 13:33:17

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29



US3782198

Folder: OL-D29 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 01:23:35

Generated On: 12 Aug 2021 13:33:17

Were vital signs assessed? Yes ☐  
No ☒

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

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

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

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

Route of measurement Oral ☐  
Axillary ☐  
Other ☐

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

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

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

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

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

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

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

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

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

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

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

US3782198

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 01:23:35

Generated On: 12 Aug 2021 13:33:17

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 FEB 2021

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

US3782198

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 01:23:35

Generated On: 12 Aug 2021 13:33:17

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 FEB 2021

Collection time (00:00-23:59)

12:25 (24 HR)

Collection date and time (derived)

23 FEB 2021 12:25

US3782198

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3782198

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

AEID	
Adverse event	EXACERBATION PSORIASIS
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)	9 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	5 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3782198

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

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

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

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PREVIOUSLY SPOKE TO  
PARTICIPANT ON 20NOV2020  
AND HE REPORTED THE RASH  
AS RED, SCATTERED,  
NON-PRURITIC RAISED BUMPS  
DISPERSED ON HIS BODY.  
PARTICIPANT REPORTS RASH  
BEGAN ON 09NOV2020 WITH 1-2  
PAPULES AND SLOWLY  
DEVELOPED ON ALL PARTS OF  
HIS BODY (EXCEPT FACE,  
HANDS, AND FEET). REVIEWED  
WITH DR KALAMS ON  
20NOV2020 AND HE URGED  
PARTICIPANT TO FOLLOW-UP  
WITH HIS PCP. SCHEDULED DR  
KALAMS TO SEE PARTICIPANT  
23NOV2020 BEFORE  
PROCEEDING WITH VISIT 2.  
NOTED ON PHYSICAL EXAM  
SCATTERED, RED,  
NON-URTICARIAL PAPULES  
(WIDESPREAD WITH ~14  
SCATTERED ON EACH  
EXTREMITY, ~20 ON TORSO, ~20  
ON BACK, A FEW IN GROIN  
AREA AND PENIS).  
PARTICIPANT REPORTS THEY  
ARE NON-PAINFUL,  
NON-PRURITIC AND  
SOMEWHAT IMPROVED (HE  
DESCRIBES AS LESS RAISED)  
AFTER HE TREATED RASH  
OVER THE WEEKEND WITH  
CLOBETASOL CREAM. THE

US3782198

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

CLOBETASOL WAS  
ORIGINALLY PRESCRIBED FOR  
HIS PSORIASIS LAST YEAR.  
NOTE PARTICIPANT STATES  
THIS RASH IS DIFFERENT FROM  
HIS PSORIASIS AS IT IS NOT  
SCALING OR DRY.  
PARTICIPANT DENIES ANY  
OTHER MEDICATIONS (SEE  
CON MED LOG) OR SYMPTOMS.  
HIS PARTNER IS HIV POSITIVE  
BUT WITH AN UNDETECTABLE  
VIRAL LOAD. THEY  
OCCASIONALLY HAVE OTHER  
PARTNERS BUT LAST TIME  
WAS ~ ONE YEAR AGO.  
DR KALAMS STATES THIS IS  
NOT VACCINE RELATED BUT  
REQUESTED WE HOLD V2  
UNTIL PARTICIPANT CAN BE  
FURTHER EVALUATED BY HIS  
PCP OR HEALTH DEPARTMENT.  
GAVE PARTICIPANT CONTACT  
INFORMATION FOR LOCAL  
HEALTH DEPARTMENT AND HE  
STATES HE WILL FOLLOW-UP  
WITH HD OR PCP.

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



US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

---

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

Yes ☒

No ☐

---

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

---

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Name of Medication IBUPROFEN

Prophylaxis Yes ☐  
No ☒

Indication OCCASIONAL BACK PAIN

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2006	
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"/>

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Name of Medication AMOXICILLIN

Prophylaxis Yes ☐  
No ☒

Indication STREP PHARYNGITIS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

	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)		17 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Name of Medication CLOBETASOL CREAM 0.05%

Prophylaxis Yes ☐  
No ☒

Indication EXACERBATION PSORIASIS

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

	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)		20 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Name of Medication BENADRYL

Prophylaxis Yes ☐  
No ☒

Indication EXACERBATION PSORIASIS

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 2 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Name of Medication ROCEPHIN

Prophylaxis Yes ☐  
No ☒

Indication EXACERBATION PSORIASIS

Dose per administration 2

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

If dose unit is Other, specify GRAM

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	2 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 2 DEC 2020		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Name of Medication ENSTILAR FOAM

Prophylaxis Yes ☐  
No ☒

Indication EXACERBATION PRORIASIS

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

	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)	2 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		14 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Name of Medication CORDRAN CREAM

Prophylaxis Yes ☐  
No ☒

Indication EXACERBATION PRORIASIS

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

	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)	2 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Name of Medication METHYLPHENIDATE ER

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 36

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

	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)	18 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3782198

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 09 Apr 2021 01:23:35

Generated On: 12 Aug 2021 13:33:17

---

Were any concomitant procedures performed?

Yes ☐

No ☒

---

If yes, please complete Concomitant Procedures form.

---

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Folder: End of Study (1)

Form: Dosing Discontinuation

Data signed: (b) (4) 26 Jan 2021 20:33:35

Generated On: 12 Aug 2021 13:33:17

Date of dosing discontinuation (dd MMM yyyy) 27 NOV 2020

Primary reason for dosing discontinuation

AE (specify)	<input type="checkbox"/>
SAE (specify)	<input type="checkbox"/>
Death	<input type="checkbox"/>
Lost To Follow-up	<input type="checkbox"/>
Physician decision (specify)	<input checked="" type="checkbox"/>
Pregnancy	<input type="checkbox"/>
Protocol deviation (specify)	<input type="checkbox"/>
Study Terminated By Sponsor	<input type="checkbox"/>
Withdrawal of consent by participant (specify)	<input type="checkbox"/>
Due to SARS-COV-2	<input type="checkbox"/>
Other	<input type="checkbox"/>

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

PHYSICIAN DECISION DUE TO RASH OF UNKNOWN ETIOLOGY AND NO MEDICAL EVALUATION AVAILABLE TO PATIENT BY PCP BEFORE WINDOW CLOSED

US3782198

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 12 Aug 2021 13:33:17

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 ☐

Audit

US3782198 (Prod: Vanderbilt University Medical Center)

**US3782198**

**Form: Participant Creation**

**Generated On: 12 Aug 2021 13:33:17**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'US3782198'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 17:48:53

**US3782198**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:33:17**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:19:00

US3782198

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '23 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 17:48:54



US3782198

Folder: Screening

Form: Visit Date

Generated On: 12 Aug 2021 13:33:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:19:00

**US3782198**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:33:17**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'SCRN'	System	23 Oct 2020 18:19:00

US3782198

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:33:17

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered (b) (6) 1990'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 17:48:55

**US3782198**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:33:17**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '30'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:19:16

**US3782198**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:33:17**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'YEARS'	System	23 Oct 2020 18:19:16

**US3782198**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:33:17**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered '30'	System	23 Oct 2020 18:19:37

**US3782198**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:33:17**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:19:16

US3782198

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:33:17

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:19:16



US3782198

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:33:17

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'I'	(b) (4), (b) (6)	23 Oct 2020 18:19:16

US3782198

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:33:17

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:19:16

**US3782198**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:33:17**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 18:19:16

**US3782198**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:33:17**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 18:19:16

**US3782198**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:33:17**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:19:16

**US3782198**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:33:17**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 18:19:16

US3782198

Folder: Screening

Form: Demographics

Generated On: 12 Aug 2021 13:33:17

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4)	(b) (4), (b) (6)

**US3782198**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:33:17**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 18:19:16



**US3782198**

**Folder: Screening**

**Form: Demographics**

**Generated On: 12 Aug 2021 13:33:17**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:19:16

US3782198

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:33:17

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:19:37

**US3782198**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:33:17**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'Oct 2020'	System	23 Oct 2020 18:19:37

**US3782198**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:33:17**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered '2020'	System	23 Oct 2020 18:19:37

**US3782198**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:33:17**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Amendment 4 (4)'	(b) (4), (b) (6)	23 Oct 2020 18:19:37

US3782198

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:33:17

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:19:37

US3782198

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:33:17

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:19:37

US3782198

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:33:17

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4)	(b) (4), (b) (6)



US3782198

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:33:17

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:19:37

US3782198

Folder: Screening

Form: Enrollment

Generated On: 12 Aug 2021 13:33:17

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 17:48:54

**US3782198**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 12 Aug 2021 13:33:17**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'I'	System	23 Oct 2020 18:19:42

US3782198

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 12 Aug 2021 13:33:17

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:19:42

US3782198

Folder: Screening

Form: Medical History Summary

Generated On: 12 Aug 2021 13:33:17

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:21:41

US3782198

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:33:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 18:23:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 18:23:43
Data point term sent to Coder	System	23 Oct 2020 18:23:07
User entered 'occasional back pain'	(b) (4), (b) (6)	23 Oct 2020 18:22:20

**US3782198**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:33:17**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'un UNK 2006'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:22:20

US3782198

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:22:20



**US3782198**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:22:20

**US3782198**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:33:17**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:22:20

**US3782198**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:22:20

US3782198

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:33:17

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'Jan 2006'	System	23 Oct 2020 18:22:20

**US3782198**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered '2006'	System	23 Oct 2020 18:22:20

US3782198

Folder: Screening

Form: Medical History (1)

Generated On: 12 Aug 2021 13:33:17

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered empty.	System	23 Oct 2020 18:22:20

**US3782198**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered empty.	System	23 Oct 2020 18:22:20

US3782198

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:33:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 18:23:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 18:23:43
Data point term sent to Coder	System	23 Oct 2020 18:23:07
User entered 'anxiety'	(b) (4), (b) (6)	23 Oct 2020 18:22:43



US3782198

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'un UNK 2008'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:22:43

US3782198

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:22:43

**US3782198**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:33:17**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:22:43

US3782198

Folder: Screening

Form: Medical History (2)

Generated On: 12 Aug 2021 13:33:17

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4)	(b) (4), (b) (6)
		23 Oct 2020 18:22:43

**US3782198**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:33:17**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:22:43

**US3782198**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:33:17**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'Jan 2008'	System	23 Oct 2020 18:22:43

**US3782198**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:33:17**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered '2008'	System	23 Oct 2020 18:22:43

**US3782198**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:33:17**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered empty.	System	23 Oct 2020 18:22:43



**US3782198**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 12 Aug 2021 13:33:17**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered empty.	System	23 Oct 2020 18:22:43

US3782198

Folder: Screening

Form: Medical History (3)

Generated On: 12 Aug 2021 13:33:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Psoriatic conditions, PT: Psoriasis, LLT: Psoriasis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 18:23:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 18:23:43
Data point term sent to Coder	System	23 Oct 2020 18:23:08
User entered 'psoriasis'	(b) (4), (b) (6)	23 Oct 2020 18:23:03

**US3782198**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:33:17**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'un UNK 2018'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:23:03

**US3782198**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:33:17**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 18:23:03

**US3782198**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:33:17**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:23:03

**US3782198**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:33:17**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4)	(b) (4), (b) (6)

**US3782198**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:33:17**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:23:03

**US3782198**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:33:17**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'Jan 2018'	System	23 Oct 2020 18:23:03



**US3782198**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:33:17**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered '2018'	System	23 Oct 2020 18:23:03

**US3782198**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:33:17**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered empty.	System	23 Oct 2020 18:23:03

**US3782198**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 12 Aug 2021 13:33:17**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered empty.	System	23 Oct 2020 18:23:03

US3782198

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:33:17

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Streptococcal infections, PT: Pharyngitis streptococcal, LLT: Streptococcal pharyngitis - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 18:24:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Oct 2020 18:24:32
Data point term sent to Coder	System	23 Oct 2020 18:24:08
User entered 'strep pharyngitis'	(b) (4), (b) (6)	23 Oct 2020 18:23:25

US3782198

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '17 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:23:25

**US3782198**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:33:17**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:23:25

**US3782198**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:33:17**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:23:25

**US3782198**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:33:17**

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4)	(b) (4), (b) (6)



US3782198

Folder: Screening

Form: Medical History (4)

Generated On: 12 Aug 2021 13:33:17

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4), (b) (6)	23 Oct 2020 18:23:25

**US3782198**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:33:17**

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'Oct 2020'	System	23 Oct 2020 18:23:25

**US3782198**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:33:17**

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered '2020'	System	23 Oct 2020 18:23:25

**US3782198**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:33:17**

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered empty.	System	23 Oct 2020 18:23:25

**US3782198**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 12 Aug 2021 13:33:17**

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered empty.	System	23 Oct 2020 18:23:25

US3782198

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:24:46

US3782198

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:24:46

**US3782198**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:17**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '12:48'	(b) (4), (b) (6)	23 Oct 2020 18:24:46



US3782198

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered '23 Oct 2020 12:48'	System	23 Oct 2020 18:24:46

US3782198

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '181' cm	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 18:24:46
DataPoint set to visible.	System	23 Oct 2020 18:19:42

US3782198

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '72.1' kg	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 18:24:46
DataPoint set to visible.	System	23 Oct 2020 18:19:42

US3782198

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered '22.00788'	System	23 Oct 2020 18:24:46
DataPoint set to visible.	System	23 Oct 2020 18:19:42

US3782198

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'kg/m2'	System	23 Oct 2020 18:24:46
DataPoint set to visible.	System	23 Oct 2020 18:19:42

US3782198

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:24:46

US3782198

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4)	(b) (4), (b) (6)

US3782198

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:24:46



US3782198

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:24:46

**US3782198**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:17**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'bpm'	System	23 Oct 2020 18:24:46

US3782198

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:24:46

**US3782198**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:17**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'breaths/min'	System	23 Oct 2020 18:24:46

US3782198

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:24:46

**US3782198**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:17**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'mmHg'	System	23 Oct 2020 18:24:46

US3782198

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:24:46

US3782198

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'mmHg'	System	23 Oct 2020 18:24:46



**US3782198**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:17**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25

US3782198

Folder: Screening

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25

US3782198

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:27:07

US3782198

Folder: Screening

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:17

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:27:07

US3782198

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:17

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:36

US3782198

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:17

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:36

US3782198

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:17

**Retail or Restaurant Operations**, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:36

US3782198

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:17

**Manufacturing & Production Operations** with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:36



US3782198

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:17

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:36

US3782198

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:17

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:36

US3782198

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:17

**Border Protection and Military Personnel** (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:36

US3782198

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:17

**Personal Care and in-home services** (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:36

US3782198

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:17

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:36

US3782198

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:17

**Pastoral, Social or Public Health Workers** requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:36

US3782198

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:17

**Educators and Students** (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:36

US3782198

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:36



US3782198

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:17

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4)	(b) (4), (b) (6)
		23 Oct 2020 18:45:36

US3782198

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:17

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:36

US3782198

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:17

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:36

US3782198

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:17

**Resides in Multi-family dwelling** (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:36

US3782198

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:17

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:36

US3782198

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:17

**Resides in low density, multi-family setting without** (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:36

US3782198

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:17

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:36

US3782198

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:17

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:36



US3782198

Folder: Screening

Form: Risk of Exposure

Generated On: 12 Aug 2021 13:33:17

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:36

US3782198

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:33:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:57

US3782198

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:57

US3782198

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 12 Aug 2021 13:33:17

[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 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:45:57

**US3782198**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:33:17**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'VISIT1'	System	23 Oct 2020 18:45:57

US3782198

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '23 OCT 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 18:03:33

US3782198

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:33:17

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '117670'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 18:03:33

US3782198

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:33:17

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	23 Oct 2020 18:03:33



US3782198

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:33:17

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 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:46:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:33:17

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 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:46:18

US3782198

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:33:17

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:46:18

US3782198

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:33:17

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:46:18

US3782198

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:33:17

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:46:18

US3782198

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 12 Aug 2021 13:33:17

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:46:18
DataPoint set to visible.	System	23 Oct 2020 18:19:37

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:46:36



US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Oct 2020 18:49:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 18:49:38
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 18:49:38
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Oct 2020 18:46:36
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 18:46:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '23 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 18:49:38
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 18:46:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '12:48' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 18:49:38
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered '23 Oct 2020 12:48'	System	23 Oct 2020 18:49:38
User entered empty.	System	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '98.4' F reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 18:49:38
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 18:46:36



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 18:49:38
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:46:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '96' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 18:49:38
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'bpm'	System	23 Oct 2020 18:49:38
User entered empty.	System	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '18' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 18:49:38
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'breaths/min'	System	23 Oct 2020 18:49:38
User entered empty.	System	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '118' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Oct 2020 18:49:38
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'mmHg'	System	23 Oct 2020 18:49:38
User entered empty.	System	23 Oct 2020 18:46:36



US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '78' reason for change: Data Entry Error	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 18:49:38
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'mmHg'	System	23 Oct 2020 18:49:38
User entered empty.	System	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Oct 2020 19:04:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Oct 2020 19:04:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Amy Kerrigan (b) (4)	23 Oct 2020 19:04:44
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	23 Oct 2020 18:46:36
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 18:46:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '23 Oct 2020' reason for change: Data Entry Error	(b) (4)	
	Amy Kerrigan (b) (4)	23 Oct 2020 19:04:44
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '13:59' reason for change: Data Entry Error	(b) (4)	
	Amy Kerrigan (b) (4)	23 Oct 2020 19:04:44
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 18:46:36



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered '23 Oct 2020 13:59'	System	23 Oct 2020 19:04:44
User entered empty.	System	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '98.1' F reason for change: Data Entry Error	(b) (4)	
	Amy Kerrigan (b) (4)	23 Oct 2020 19:04:44
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Amy Kerrigan (b) (4)	23 Oct 2020 19:04:44
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '100' reason for change: Data Entry Error	(b) (4) Amy Kerrigan (b) (4)	23 Oct 2020 19:04:44
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 18:46:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'bpm'	System	23 Oct 2020 19:04:44
User entered empty.	System	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '16' reason for change: Data Entry Error	(b) (4)	
	Amy Kerrigan (b) (4)	23 Oct 2020 19:04:44
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 18:46:36

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'breaths/min'	System	23 Oct 2020 19:04:44
User entered empty.	System	23 Oct 2020 18:46:36



US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '108' reason for change: Data Entry Error	(b) (4) Amy Kerrigan (b) (4)	23 Oct 2020 19:04:44
User entered empty.	(b) (4), (b) (6)	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'mmHg'	System	23 Oct 2020 19:04:44
User entered empty.	System	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '82' reason for change: Data Entry Error	(b) (4)	
	Amy Kerrigan (b) (4)	23 Oct 2020 19:04:44
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'mmHg'	System	23 Oct 2020 19:04:44
User entered empty.	System	23 Oct 2020 18:46:36

US3782198

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:49:53

US3782198

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:17

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:49:53

US3782198

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:50:27

US3782198

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:50:27



US3782198

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

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 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:50:27

US3782198

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'MRNA-1273 OR PLACEBO'	System	23 Oct 2020 18:50:27

US3782198

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:50:27

US3782198

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '13:29'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:50:27

US3782198

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered '23 Oct 2020 13:29'	System	23 Oct 2020 18:50:27

US3782198

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:50:27

US3782198

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'ONCE'	System	23 Oct 2020 18:50:27

US3782198

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'INTRAMUSCULAR'	System	23 Oct 2020 18:50:27



US3782198

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:50:48

US3782198

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:50:48

US3782198

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '12:56'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:50:48

US3782198

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered '23 Oct 2020 12:56'	System	23 Oct 2020 18:50:48

US3782198

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:33:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:51:06

US3782198

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:33:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	23 Oct 2020 18:51:06

US3782198

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:51:06

US3782198

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:33:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '12:58'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:51:06



**US3782198**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered '23 Oct 2020 12:58'	System	23 Oct 2020 18:51:06

US3782198

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:33:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	23 Oct 2020 18:51:06

US3782198

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:51:06

US3782198

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:33:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:51:06

**US3782198**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:33:17**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered empty.	System	23 Oct 2020 18:51:06

US3782198

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 18:51:11

US3782198

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered '1'	System	23 Oct 2020 18:51:11

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Oct 2020 18:50:27



US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T14:03:57', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'd15a1a54-5155-46ac-8890-95e81193015e' User entered 'Yes (Y)'	System	23 Oct 2020 19:04:26
	System	23 Oct 2020 19:04:26

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T14:04:04', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'd15a1a54-5155-46ac-8890-95e81193015e' User entered '98.1'	System	23 Oct 2020 19:04:26
	System	23 Oct 2020 19:04:26

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T14:04:13', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'd15a1a54-5155-46ac-8890-95e81193015e' User entered 'No (N)'	System	23 Oct 2020 19:04:26
	System	23 Oct 2020 19:04:26

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T14:04:21', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'd15a1a54-5155-46ac-8890-95e81193015e' User entered '23 Oct 2020 14:04'	System	23 Oct 2020 19:04:26
	System	23 Oct 2020 19:04:26

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '23 Oct 2020 13:49'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '23 Oct 2020 16:19'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 1, after vaccination (at home)'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T19:23:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '1d9af7fe-3a92-485a-9344-e460bd5db0c0' User entered 'Yes (Y)'	System	24 Oct 2020 00:23:25
	System	24 Oct 2020 00:23:25



US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T19:23:14', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '1d9af7fe-3a92-485a-9344-e460bd5db0c0' User entered '98.2'	System	24 Oct 2020 00:23:25
	System	24 Oct 2020 00:23:25

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T19:23:17', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '1d9af7fe-3a92-485a-9344-e460bd5db0c0' User entered 'No (N)'	System	24 Oct 2020 00:23:25
	System	24 Oct 2020 00:23:25

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T19:23:21', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '1d9af7fe-3a92-485a-9344-e460bd5db0c0' User entered '23 Oct 2020 19:23'	System	24 Oct 2020 00:23:25
	System	24 Oct 2020 00:23:25

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '23 Oct 2020 17:14'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 2'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-24T17:14:47', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '4e0de9a5-bb17-4545-89ba-e32f7b0c3619' User entered 'Yes (Y)'	System	24 Oct 2020 22:15:03
	System	24 Oct 2020 22:15:03

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-24T17:14:51', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '4e0de9a5-bb17-4545-89ba-e32f7b0c3619' User entered '98.5'	System	24 Oct 2020 22:15:03
	System	24 Oct 2020 22:15:03



US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-24T17:14:55', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '4e0de9a5-bb17-4545-89ba-e32f7b0c3619' User entered 'No (N)'	System	24 Oct 2020 22:15:03
	System	24 Oct 2020 22:15:03

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-24T17:14:59', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '4e0de9a5-bb17-4545-89ba-e32f7b0c3619' User entered '24 Oct 2020 17:14'	System	24 Oct 2020 22:15:03
	System	24 Oct 2020 22:15:03

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 3'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T08:15:14', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '61129114-ca0a-4306-97d4-0bca61367484' User entered 'Yes (Y)'	System	26 Oct 2020 13:15:29
	System	26 Oct 2020 13:15:29

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T08:15:19', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '61129114-ca0a-4306-97d4-0bca61367484' User entered '98.5'	System	26 Oct 2020 13:15:29
	System	26 Oct 2020 13:15:29

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T08:15:23', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '61129114-ca0a-4306-97d4-0bca61367484' User entered 'No (N)'	System	26 Oct 2020 13:15:29
	System	26 Oct 2020 13:15:29



US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T08:15:26', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '61129114-ca0a-4306-97d4-0bca61367484' User entered '26 Oct 2020 08:15'	System	26 Oct 2020 13:15:29
	System	26 Oct 2020 13:15:29

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 4'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T19:00:49', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '78778919-c053-4b32-9ac6-d3c3839c0985'	System	27 Oct 2020 00:01:06
User entered 'Yes (Y)'	System	27 Oct 2020 00:01:06

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T19:00:53', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '78778919-c053-4b32-9ac6-d3c3839c0985' User entered '98.4'	System	27 Oct 2020 00:01:06
	System	27 Oct 2020 00:01:06

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T19:00:56', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '78778919-c053-4b32-9ac6-d3c3839c0985'	System	27 Oct 2020 00:01:06
User entered 'No (N)'	System	27 Oct 2020 00:01:06

**US3782198**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 12 Aug 2021 13:33:17**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T19:01:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '78778919-c053-4b32-9ac6-d3c3839c0985' User entered '26 Oct 2020 19:01'	System	27 Oct 2020 00:01:06
	System	27 Oct 2020 00:01:06



US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '26 Oct 2020 12:00'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '27 Oct 2020 11:59'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 5'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-27T17:53:48', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'c35884cd-2198-42c8-b891-f9d823436d7a' User entered 'Yes (Y)'	System	27 Oct 2020 22:54:02
	System	27 Oct 2020 22:54:02

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-27T17:53:52', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'c35884cd-2198-42c8-b891-f9d823436d7a' User entered '98.9'	System	27 Oct 2020 22:54:02
	System	27 Oct 2020 22:54:02

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-27T17:53:57', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'c35884cd-2198-42c8-b891-f9d823436d7a' User entered 'No (N)'	System	27 Oct 2020 22:54:02
	System	27 Oct 2020 22:54:02

**US3782198**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 12 Aug 2021 13:33:17**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-27T17:54:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'c35884cd-2198-42c8-b891-f9d823436d7a' User entered '27 Oct 2020 17:54'	System	27 Oct 2020 22:54:02
	System	27 Oct 2020 22:54:02

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '27 Oct 2020 12:00'	System	23 Oct 2020 18:50:27



US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '28 Oct 2020 11:59'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 6'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-28T17:30:59', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '1d961d84-9a8e-4545-a5af-f484400f30d6' User entered 'Yes (Y)'	System	28 Oct 2020 22:31:09
	System	28 Oct 2020 22:31:09

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-28T17:31:02', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '1d961d84-9a8e-4545-a5af-f484400f30d6' User entered '98.5'	System	28 Oct 2020 22:31:09
	System	28 Oct 2020 22:31:09

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-28T17:31:05', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '1d961d84-9a8e-4545-a5af-f484400f30d6'	System	28 Oct 2020 22:31:09
User entered 'No (N)'	System	28 Oct 2020 22:31:09

**US3782198**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 12 Aug 2021 13:33:17**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-28T17:31:07', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '1d961d84-9a8e-4545-a5af-f484400f30d6' User entered '28 Oct 2020 17:31'	System	28 Oct 2020 22:31:09
	System	28 Oct 2020 22:31:09

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '28 Oct 2020 12:00'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '29 Oct 2020 11:59'	System	23 Oct 2020 18:50:27



US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 7'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:33:17

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-29T16:45:02', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'cd786001-a1d6-4847-b70d-8eb65d403e44'	System	29 Oct 2020 21:45:19
User entered 'Yes (Y)'	System	29 Oct 2020 21:45:19

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:33:17

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-29T16:45:09', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'cd786001-a1d6-4847-b70d-8eb65d403e44' User entered '97.1'	System	29 Oct 2020 21:45:19
	System	29 Oct 2020 21:45:19

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-29T16:45:13', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'cd786001-a1d6-4847-b70d-8eb65d403e44'	System	29 Oct 2020 21:45:19
User entered 'No (N)'	System	29 Oct 2020 21:45:19

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-29T16:45:15', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'cd786001-a1d6-4847-b70d-8eb65d403e44'	System	29 Oct 2020 21:45:19
User entered '29 Oct 2020 16:45'	System	29 Oct 2020 21:45:19

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '29 Oct 2020 12:00'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '30 Oct 2020 11:59'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Oct 2020 18:50:27



US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T14:04:42', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '83725dd9-c912-4611-ae6b-b5d5f9402742'	System	23 Oct 2020 19:05:02
User entered 'None (1)'	System	23 Oct 2020 19:05:02

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T14:04:45', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '83725dd9-c912-4611-ae6b-b5d5f9402742' User entered 'No (N)'	System	23 Oct 2020 19:05:02
	System	23 Oct 2020 19:05:02

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T14:04:48', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '83725dd9-c912-4611-ae6b-b5d5f9402742' User entered 'No (N)'	System	23 Oct 2020 19:05:02
	System	23 Oct 2020 19:05:02

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T14:04:54', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '83725dd9-c912-4611-ae6b-b5d5f9402742'	System	23 Oct 2020 19:05:02
User entered 'None (1)'	System	23 Oct 2020 19:05:02

**US3782198**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 12 Aug 2021 13:33:17**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T14:04:59', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '83725dd9-c912-4611-ae6b-b5d5f9402742' User entered '23 Oct 2020 14:04'	System	23 Oct 2020 19:05:02
	System	23 Oct 2020 19:05:02

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '23 Oct 2020 13:49'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '23 Oct 2020 16:19'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 1, after vaccination (at home)'	System	23 Oct 2020 18:50:27



US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T19:23:28', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '180ca452-f12c-4ceb-9c8e-dab6732aa43b' User entered 'None (1)'	System	24 Oct 2020 00:23:47
	System	24 Oct 2020 00:23:47

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T19:23:31', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '180ca452-f12c-4ceb-9c8e-dab6732aa43b' User entered 'No (N)'	System	24 Oct 2020 00:23:47
	System	24 Oct 2020 00:23:47

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T19:23:33', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '180ca452-f12c-4ceb-9c8e-dab6732aa43b' User entered 'No (N)'	System	24 Oct 2020 00:23:47
	System	24 Oct 2020 00:23:47

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T19:23:37', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '180ca452-f12c-4ceb-9c8e-dab6732aa43b' User entered 'None (1)'	System	24 Oct 2020 00:23:47
	System	24 Oct 2020 00:23:47

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T19:23:42', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '180ca452-f12c-4ceb-9c8e-dab6732aa43b' User entered '23 Oct 2020 19:23'	System	24 Oct 2020 00:23:47
	System	24 Oct 2020 00:23:47

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '23 Oct 2020 17:14'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 2'	System	23 Oct 2020 18:50:27



US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-24T17:15:08', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'a10c05ea-390c-4e63-bc1b-77720b780d7d' User entered 'Does not interfere with activity (2)'	System	24 Oct 2020 22:15:25
	System	24 Oct 2020 22:15:25

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-24T17:15:12', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'a10c05ea-390c-4e63-bc1b-77720b780d7d' User entered 'No (N)'	System	24 Oct 2020 22:15:25
	System	24 Oct 2020 22:15:25

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-24T17:15:15', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'a10c05ea-390c-4e63-bc1b-77720b780d7d' User entered 'No (N)'	System	24 Oct 2020 22:15:25
	System	24 Oct 2020 22:15:25

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-24T17:15:18', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'a10c05ea-390c-4e63-bc1b-77720b780d7d' User entered 'None (1)'	System	24 Oct 2020 22:15:25
	System	24 Oct 2020 22:15:25

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-24T17:15:22', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'a10c05ea-390c-4e63-bc1b-77720b780d7d' User entered '24 Oct 2020 17:15'	System	24 Oct 2020 22:15:25
	System	24 Oct 2020 22:15:25

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 3'	System	23 Oct 2020 18:50:27



US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T08:15:29', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '8f445881-47c7-49c4-8b62-0fcdb2ea20f8' User entered 'None (1)'	System	26 Oct 2020 13:15:46
	System	26 Oct 2020 13:15:46

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T08:15:32', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '8f445881-47c7-49c4-8b62-0fcdb2ea20f8' User entered 'No (N)'	System	26 Oct 2020 13:15:46
	System	26 Oct 2020 13:15:46

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T08:15:36', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '8f445881-47c7-49c4-8b62-0fcdb2ea20f8' User entered 'No (N)'	System	26 Oct 2020 13:15:46
	System	26 Oct 2020 13:15:46

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T08:15:40', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '8f445881-47c7-49c4-8b62-0fcdb2ea20f8'	System	26 Oct 2020 13:15:46
User entered 'None (1)'	System	26 Oct 2020 13:15:46

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T08:15:44', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '8f445881-47c7-49c4-8b62-0fcbd2ea20f8' User entered '26 Oct 2020 08:15'	System	26 Oct 2020 13:15:46
	System	26 Oct 2020 13:15:46

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 4'	System	23 Oct 2020 18:50:27



US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T19:01:06', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '10cfc715-7518-44b6-9eb7-f49a513bc489'	System	27 Oct 2020 00:01:24
User entered 'None (1)'	System	27 Oct 2020 00:01:24

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T19:01:09', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '10cfc715-7518-44b6-9eb7-f49a513bc489' User entered 'No (N)'	System	27 Oct 2020 00:01:24
	System	27 Oct 2020 00:01:24

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T19:01:11', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '10cfc715-7518-44b6-9eb7-f49a513bc489'	System	27 Oct 2020 00:01:24
User entered 'No (N)'	System	27 Oct 2020 00:01:24

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T19:01:14', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '10cfc715-7518-44b6-9eb7-f49a513bc489'	System	27 Oct 2020 00:01:24
User entered 'None (1)'	System	27 Oct 2020 00:01:24

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T19:01:18', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '10cfc715-7518-44b6-9eb7-f49a513bc489' User entered '26 Oct 2020 19:01'	System	27 Oct 2020 00:01:24
	System	27 Oct 2020 00:01:24

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '26 Oct 2020 12:00'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '27 Oct 2020 11:59'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 5'	System	23 Oct 2020 18:50:27



US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-27T17:54:03', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'ffa25b1a-8cbc-40d9-a154-b31a73e4d36e' User entered 'None (1)'	System	27 Oct 2020 22:54:14
	System	27 Oct 2020 22:54:14

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-27T17:54:06', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'ffa25b1a-8cbc-40d9-a154-b31a73e4d36e' User entered 'No (N)'	System	27 Oct 2020 22:54:14
	System	27 Oct 2020 22:54:14

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-27T17:54:08', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'ffa25b1a-8cbc-40d9-a154-b31a73e4d36e' User entered 'No (N)'	System	27 Oct 2020 22:54:14
	System	27 Oct 2020 22:54:14

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-27T17:54:11', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'ffa25b1a-8cbc-40d9-a154-b31a73e4d36e' User entered 'None (1)'	System	27 Oct 2020 22:54:14
	System	27 Oct 2020 22:54:14

**US3782198**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 12 Aug 2021 13:33:17**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-27T17:54:13', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'ffa25b1a-8cbc-40d9-a154-b31a73e4d36e' User entered '27 Oct 2020 17:54'	System	27 Oct 2020 22:54:14
	System	27 Oct 2020 22:54:14

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '27 Oct 2020 12:00'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '28 Oct 2020 11:59'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 6'	System	23 Oct 2020 18:50:27



US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-28T17:31:10', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'f86ca952-6397-4307-84ce-97c3e5f080ff' User entered 'None (1)'	System	28 Oct 2020 22:31:23
	System	28 Oct 2020 22:31:23

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-28T17:31:11', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'f86ca952-6397-4307-84ce-97c3e5f080ff' User entered 'No (N)'	System	28 Oct 2020 22:31:23
	System	28 Oct 2020 22:31:23

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-28T17:31:14', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'f86ca952-6397-4307-84ce-97c3e5f080ff' User entered 'No (N)'	System	28 Oct 2020 22:31:23
	System	28 Oct 2020 22:31:23

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-28T17:31:15', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'f86ca952-6397-4307-84ce-97c3e5f080ff' User entered 'None (1)'	System	28 Oct 2020 22:31:23
	System	28 Oct 2020 22:31:23

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-28T17:31:17', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'f86ca952-6397-4307-84ce-97c3e5f080ff' User entered '28 Oct 2020 17:31'	System	28 Oct 2020 22:31:23
	System	28 Oct 2020 22:31:23

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '28 Oct 2020 12:00'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '29 Oct 2020 11:59'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 7'	System	23 Oct 2020 18:50:27



US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-29T16:45:18', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'c10b42ec-1295-46ce-a13c-9ba329bfa3df' User entered 'None (1)'	System	29 Oct 2020 21:45:33
	System	29 Oct 2020 21:45:33

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:33:17

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-29T16:45:21', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'c10b42ec-1295-46ce-a13c-9ba329bfa3df' User entered 'No (N)'	System	29 Oct 2020 21:45:33
	System	29 Oct 2020 21:45:33

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-29T16:45:23', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'c10b42ec-1295-46ce-a13c-9ba329bfa3df' User entered 'No (N)'	System	29 Oct 2020 21:45:33
	System	29 Oct 2020 21:45:33

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:33:17

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-29T16:45:25', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'c10b42ec-1295-46ce-a13c-9ba329bfa3df' User entered 'None (1)'	System	29 Oct 2020 21:45:33
	System	29 Oct 2020 21:45:33

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:33:17

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-29T16:45:28', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'c10b42ec-1295-46ce-a13c-9ba329bfa3df' User entered '29 Oct 2020 16:45'	System	29 Oct 2020 21:45:33
	System	29 Oct 2020 21:45:33

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '29 Oct 2020 12:00'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '30 Oct 2020 11:59'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Oct 2020 18:50:27



US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T14:05:13', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'd159b13a-e9e4-4463-b279-ba0800007d88' User entered 'None (0)'	System	23 Oct 2020 19:05:51
	System	23 Oct 2020 19:05:51

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T14:05:20', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'd159b13a-e9e4-4463-b279-ba0800007d88' User entered 'None (0)'	System	23 Oct 2020 19:05:51
	System	23 Oct 2020 19:05:51

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T14:05:24', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'd159b13a-e9e4-4463-b279-ba0800007d88' User entered 'None (0)'	System	23 Oct 2020 19:05:51
	System	23 Oct 2020 19:05:51

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T14:05:28', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'd159b13a-e9e4-4463-b279-ba0800007d88' User entered 'None (0)'	System	23 Oct 2020 19:05:51
	System	23 Oct 2020 19:05:51

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T14:05:31', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'd159b13a-e9e4-4463-b279-ba0800007d88' User entered 'None (0)'	System	23 Oct 2020 19:05:51
	System	23 Oct 2020 19:05:51

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T14:05:33', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'd159b13a-e9e4-4463-b279-ba0800007d88' User entered 'None (0)'	System	23 Oct 2020 19:05:51
	System	23 Oct 2020 19:05:51

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

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)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T14:05:44', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'd159b13a-e9e4-4463-b279-ba0800007d88'	System	23 Oct 2020 19:05:51
User entered 'No (N)'	System	23 Oct 2020 19:05:51

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T14:05:48', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'd159b13a-e9e4-4463-b279-ba0800007d88'	System	23 Oct 2020 19:05:51
User entered '23 Oct 2020 14:05'	System	23 Oct 2020 19:05:51



US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '23 Oct 2020 13:49'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '23 Oct 2020 16:19'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 1, after vaccination (at home)'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T19:23:47', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '7a0cd32d-2ac7-436b-8423-3cf10989ebe3' User entered 'None (0)'	System	24 Oct 2020 00:24:15
	System	24 Oct 2020 00:24:15

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T19:23:54', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '7a0cd32d-2ac7-436b-8423-3cf10989ebe3'	System	24 Oct 2020 00:24:15
User entered 'No interference with activity (1)'	System	24 Oct 2020 00:24:15

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T19:23:58', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '7a0cd32d-2ac7-436b-8423-3cf10989ebe3' User entered 'None (0)'	System	24 Oct 2020 00:24:15
	System	24 Oct 2020 00:24:15

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T19:24:02', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '7a0cd32d-2ac7-436b-8423-3cf10989ebe3' User entered 'None (0)'	System	24 Oct 2020 00:24:15
	System	24 Oct 2020 00:24:15

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T19:24:05', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '7a0cd32d-2ac7-436b-8423-3cf10989ebe3' User entered 'None (0)'	System	24 Oct 2020 00:24:15
	System	24 Oct 2020 00:24:15



US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T19:24:07', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '7a0cd32d-2ac7-436b-8423-3cf10989ebe3' User entered 'None (0)'	System	24 Oct 2020 00:24:15
	System	24 Oct 2020 00:24:15

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

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)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T19:24:09', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '7a0cd32d-2ac7-436b-8423-3cf10989ebe3' User entered 'No (N)'	System	24 Oct 2020 00:24:15
	System	24 Oct 2020 00:24:15

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-23T19:24:11', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '7a0cd32d-2ac7-436b-8423-3cf10989ebe3' User entered '23 Oct 2020 19:24'	System	24 Oct 2020 00:24:15
	System	24 Oct 2020 00:24:15

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '23 Oct 2020 17:14'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '24 Oct 2020 11:59'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 2'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-24T17:15:26', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '3c0ec72f-888d-4dc6-a453-d34cee9ec4ef'	System	24 Oct 2020 22:15:43
User entered 'No interference with activity (1)'	System	24 Oct 2020 22:15:43

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-24T17:15:28', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '3c0ec72f-888d-4dc6-a453-d34cee9ec4ef' User entered 'None (0)'	System	24 Oct 2020 22:15:43
	System	24 Oct 2020 22:15:43



US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-24T17:15:31', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '3c0ec72f-888d-4dc6-a453-d34cee9ec4ef' User entered 'None (0)'	System	24 Oct 2020 22:15:43
	System	24 Oct 2020 22:15:43

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-24T17:15:33', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '3c0ec72f-888d-4dc6-a453-d34cee9ec4ef' User entered 'None (0)'	System	24 Oct 2020 22:15:43
	System	24 Oct 2020 22:15:43

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-24T17:15:35', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '3c0ec72f-888d-4dc6-a453-d34cee9ec4ef' User entered 'None (0)'	System	24 Oct 2020 22:15:43
	System	24 Oct 2020 22:15:43

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-24T17:15:37', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '3c0ec72f-888d-4dc6-a453-d34cee9ec4ef' User entered 'None (0)'	System	24 Oct 2020 22:15:43
	System	24 Oct 2020 22:15:43

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:33:17

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)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-24T17:15:39', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '3c0ec72f-888d-4dc6-a453-d34cee9ec4ef' User entered 'No (N)'	System	24 Oct 2020 22:15:43
	System	24 Oct 2020 22:15:43

**US3782198**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 12 Aug 2021 13:33:17**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-24T17:15:41', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '3c0ec72f-888d-4dc6-a453-d34cee9ec4ef' User entered '24 Oct 2020 17:15'	System	24 Oct 2020 22:15:43
	System	24 Oct 2020 22:15:43

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '24 Oct 2020 12:00'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '25 Oct 2020 11:59'	System	23 Oct 2020 18:50:27



US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 3'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T08:16:01', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '59b9e54b-86f1-407f-94e7-2111cd9fe759'	System	26 Oct 2020 13:16:33
User entered 'No interference with activity (1)'	System	26 Oct 2020 13:16:33

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T08:16:05', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '59b9e54b-86f1-407f-94e7-2111cd9fe759' User entered 'None (0)'	System	26 Oct 2020 13:16:33
	System	26 Oct 2020 13:16:33

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T08:16:08', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '59b9e54b-86f1-407f-94e7-2111cd9fe759' User entered 'None (0)'	System	26 Oct 2020 13:16:33
	System	26 Oct 2020 13:16:33

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T08:16:11', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '59b9e54b-86f1-407f-94e7-2111cd9fe759' User entered 'None (0)'	System	26 Oct 2020 13:16:33
	System	26 Oct 2020 13:16:33

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T08:16:18', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '59b9e54b-86f1-407f-94e7-2111cd9fe759' User entered 'None (0)'	System	26 Oct 2020 13:16:33
	System	26 Oct 2020 13:16:33

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T08:16:26', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '59b9e54b-86f1-407f-94e7-2111cd9fe759' User entered 'None (0)'	System	26 Oct 2020 13:16:33
	System	26 Oct 2020 13:16:33

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:33:17

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)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T08:16:29', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '59b9e54b-86f1-407f-94e7-2111cd9fe759' User entered 'No (N)'	System	26 Oct 2020 13:16:33
	System	26 Oct 2020 13:16:33



**US3782198**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 12 Aug 2021 13:33:17**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T08:16:32', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '59b9e54b-86f1-407f-94e7-2111cd9fe759' User entered '26 Oct 2020 08:16'	System	26 Oct 2020 13:16:33
	System	26 Oct 2020 13:16:33

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '25 Oct 2020 12:00'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '26 Oct 2020 11:59'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 4'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T19:01:23', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'd214a4ed-cc28-463f-b7d6-0cd3259fb787' User entered 'None (0)'	System	27 Oct 2020 00:01:45
	System	27 Oct 2020 00:01:45

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T19:01:26', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'd214a4ed-cc28-463f-b7d6-0cd3259fb787' User entered 'None (0)'	System	27 Oct 2020 00:01:45
	System	27 Oct 2020 00:01:45

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T19:01:30', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'd214a4ed-cc28-463f-b7d6-0cd3259fb787' User entered 'None (0)'	System	27 Oct 2020 00:01:45
	System	27 Oct 2020 00:01:45

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T19:01:32', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'd214a4ed-cc28-463f-b7d6-0cd3259fb787' User entered 'None (0)'	System	27 Oct 2020 00:01:45
	System	27 Oct 2020 00:01:45



US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T19:01:34', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'd214a4ed-cc28-463f-b7d6-0cd3259fb787' User entered 'None (0)'	System	27 Oct 2020 00:01:45
	System	27 Oct 2020 00:01:45

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T19:01:36', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'd214a4ed-cc28-463f-b7d6-0cd3259fb787' User entered 'None (0)'	System	27 Oct 2020 00:01:45
	System	27 Oct 2020 00:01:45

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:17

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)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T19:01:39', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'd214a4ed-cc28-463f-b7d6-0cd3259fb787' User entered 'No (N)'	System	27 Oct 2020 00:01:45
	System	27 Oct 2020 00:01:45

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-26T19:01:42', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'd214a4ed-cc28-463f-b7d6-0cd3259fb787' User entered '26 Oct 2020 19:01'	System	27 Oct 2020 00:01:45
	System	27 Oct 2020 00:01:45

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '26 Oct 2020 12:00'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '27 Oct 2020 11:59'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 5'	System	23 Oct 2020 18:50:27

**US3782198**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 12 Aug 2021 13:33:17**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-27T17:54:17', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'a37489d7-a79c-404e-912d-2ad9dde25802'	System	27 Oct 2020 22:54:58
User entered 'No interference with activity (1)'	System	27 Oct 2020 22:54:58



US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-27T17:54:21', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'a37489d7-a79c-404e-912d-2ad9dde25802'	System	27 Oct 2020 22:54:58
User entered 'No interference with activity (1)'	System	27 Oct 2020 22:54:58

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-27T17:54:26', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'a37489d7-a79c-404e-912d-2ad9dde25802' User entered 'None (0)'	System	27 Oct 2020 22:54:58
	System	27 Oct 2020 22:54:58

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-27T17:54:31', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'a37489d7-a79c-404e-912d-2ad9dde25802' User entered 'None (0)'	System	27 Oct 2020 22:54:58
	System	27 Oct 2020 22:54:58

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-27T17:54:40', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'a37489d7-a79c-404e-912d-2ad9dde25802' User entered 'None (0)'	System	27 Oct 2020 22:54:58
	System	27 Oct 2020 22:54:58

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-27T17:54:41', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'a37489d7-a79c-404e-912d-2ad9dde25802' User entered 'None (0)'	System	27 Oct 2020 22:54:58
	System	27 Oct 2020 22:54:58

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:17

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)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-27T17:54:53', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'a37489d7-a79c-404e-912d-2ad9dde25802' User entered 'No (N)'	System	27 Oct 2020 22:54:58
	System	27 Oct 2020 22:54:58

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-27T17:54:55', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'a37489d7-a79c-404e-912d-2ad9dde25802' User entered '27 Oct 2020 17:54'	System	27 Oct 2020 22:54:58
	System	27 Oct 2020 22:54:58

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '27 Oct 2020 12:00'	System	23 Oct 2020 18:50:27



US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '28 Oct 2020 11:59'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 6'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-28T17:31:20', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '50299666-4b12-4781-9b47-57c0663b5f8a' User entered 'None (0)'	System	28 Oct 2020 22:31:32
	System	28 Oct 2020 22:31:32

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-28T17:31:21', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '50299666-4b12-4781-9b47-57c0663b5f8a' User entered 'None (0)'	System	28 Oct 2020 22:31:32
	System	28 Oct 2020 22:31:32

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-28T17:31:22', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '50299666-4b12-4781-9b47-57c0663b5f8a' User entered 'None (0)'	System	28 Oct 2020 22:31:32
	System	28 Oct 2020 22:31:32

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-28T17:31:23', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '50299666-4b12-4781-9b47-57c0663b5f8a' User entered 'None (0)'	System	28 Oct 2020 22:31:32
	System	28 Oct 2020 22:31:32

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-28T17:31:25', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '50299666-4b12-4781-9b47-57c0663b5f8a' User entered 'None (0)'	System	28 Oct 2020 22:31:32
	System	28 Oct 2020 22:31:32

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-28T17:31:26', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '50299666-4b12-4781-9b47-57c0663b5f8a' User entered 'None (0)'	System	28 Oct 2020 22:31:32
	System	28 Oct 2020 22:31:32



US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:17

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)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-28T17:31:27', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '50299666-4b12-4781-9b47-57c0663b5f8a' User entered 'No (N)'	System	28 Oct 2020 22:31:32
	System	28 Oct 2020 22:31:32

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-28T17:31:29', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '50299666-4b12-4781-9b47-57c0663b5f8a' User entered '28 Oct 2020 17:31'	System	28 Oct 2020 22:31:32
	System	28 Oct 2020 22:31:32

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '28 Oct 2020 12:00'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '29 Oct 2020 11:59'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	23 Oct 2020 18:50:27
User entered 'Day 7'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:17

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-29T16:45:33', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'ee5f614f-2bd7-4937-808d-ab9810e40afd' User entered 'No interference with activity (1)'	System	29 Oct 2020 21:45:56
	System	29 Oct 2020 21:45:56

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:17

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-29T16:45:36', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'ee5f614f-2bd7-4937-808d-ab9810e40afd' User entered 'None (0)'	System	29 Oct 2020 21:45:56
	System	29 Oct 2020 21:45:56

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:17

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-29T16:45:38', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'ee5f614f-2bd7-4937-808d-ab9810e40afd' User entered 'None (0)'	System	29 Oct 2020 21:45:56
	System	29 Oct 2020 21:45:56



US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:17

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-29T16:45:40', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'ee5f614f-2bd7-4937-808d-ab9810e40afd' User entered 'None (0)'	System	29 Oct 2020 21:45:56
	System	29 Oct 2020 21:45:56

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:17

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-29T16:45:44', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'ee5f614f-2bd7-4937-808d-ab9810e40afd' User entered 'None (0)'	System	29 Oct 2020 21:45:56
	System	29 Oct 2020 21:45:56

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:17

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-29T16:45:47', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'ee5f614f-2bd7-4937-808d-ab9810e40afd' User entered 'None (0)'	System	29 Oct 2020 21:45:56
	System	29 Oct 2020 21:45:56

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:17

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)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-29T16:45:50', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'ee5f614f-2bd7-4937-808d-ab9810e40afd' User entered 'No (N)'	System	29 Oct 2020 21:45:56
	System	29 Oct 2020 21:45:56

**US3782198**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 12 Aug 2021 13:33:17**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-29T16:45:53', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'ee5f614f-2bd7-4937-808d-ab9810e40afd' User entered '29 Oct 2020 16:45'	System	29 Oct 2020 21:45:56
	System	29 Oct 2020 21:45:56

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '29 Oct 2020 12:00'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '30 Oct 2020 11:59'	System	23 Oct 2020 18:50:27

US3782198

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	29 Oct 2020 21:45:56
User entered 'Day 8'	System	29 Oct 2020 21:45:56



US3782198

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 12 Aug 2021 13:33:17

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-31T08:13:14', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'e8fce534-3834-4cdf-94a2-a19d95d9db89' User entered 'None (0)'	System	31 Oct 2020 12:13:20
	System	31 Oct 2020 12:13:20

**US3782198**

**Folder: Diary Dose 1 (1)**

**Form: Headache\_Day(8)**

**Generated On: 12 Aug 2021 13:33:17**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-31T08:13:17', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'e8fce534-3834-4cdf-94a2-a19d95d9db89' User entered '31 Oct 2020 08:13'	System	31 Oct 2020 12:13:20
	System	31 Oct 2020 12:13:20

US3782198

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '30 Oct 2020 12:00'	System	29 Oct 2020 21:45:56

US3782198

Folder: Diary Dose 1 (1)

Form: Headache\_Day(8)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '31 Oct 2020 11:59'	System	29 Oct 2020 21:45:56

US3782198

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 12 Aug 2021 13:33:17

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
Data entry locked.	System	29 Oct 2020 21:45:56
User entered 'Day 8'	System	29 Oct 2020 21:45:56

US3782198

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 12 Aug 2021 13:33:17

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)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-31T08:13:20', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'bdff6f0e-1e9f-4e99-a6da-0e5bef58bcc6'	System	31 Oct 2020 12:13:24
User entered 'No (N)'	System	31 Oct 2020 12:13:24

US3782198

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 12 Aug 2021 13:33:17

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (7BF4DEBD-55EA-4B49-A8BC-C1274F8ECE85)', Time: '2020-10-31T08:13:22', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'bdf6f0e-1e9f-4e99-a6da-0e5bef58bcc6'	System	31 Oct 2020 12:13:24
User entered '31 Oct 2020 08:13'	System	31 Oct 2020 12:13:24

US3782198

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 12 Aug 2021 13:33:17

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '30 Oct 2020 12:00'	System	29 Oct 2020 21:45:56



US3782198

Folder: Diary Dose 1 (1)

Form: Medical Attention\_Day(8)

Generated On: 12 Aug 2021 13:33:17

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:05:39
User entered '31 Oct 2020 11:59'	System	29 Oct 2020 21:45:56

US3782198

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:37:49

US3782198

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '30 Oct 2020'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:37:49

US3782198

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:37:49

US3782198

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:37:49

US3782198

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Oct 2020 12:37:56

US3782198

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'I'	System	30 Oct 2020 12:37:56

**US3782198**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:17**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:30:25



US3782198

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '6 Nov 2020'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:30:25

**US3782198**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:17**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:30:25

US3782198

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:30:25

US3782198

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Nov 2020 14:30:15

US3782198

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'I'	System	06 Nov 2020 14:30:15

**US3782198**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:17**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:01:16

US3782198

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '13 Nov 2020'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:01:16

US3782198

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:01:16



**US3782198**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:17**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Nov 2020 18:01:16

US3782198

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Nov 2020 17:31:18

US3782198

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'I'	System	13 Nov 2020 17:31:18

US3782198

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:33:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	27 Nov 2020 17:03:58

US3782198

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered '27 Nov 2020'	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:03:58

US3782198

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:33:17

[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 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered 'Clinic (Clinic)'	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:03:58

**US3782198**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:33:17**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'VISIT2'	System	27 Nov 2020 17:03:58

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User accepted default value 'Pre-Dose (PREDOSE)'	Carlton Griffin (b) (4) (b) (4)	27 Nov 2020 17:38:06



US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:38:06

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered '27 Nov 2020'	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:38:06
	(b) (4)	

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered '11:20'	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:38:06

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered '27 Nov 2020 11:20'	System	27 Nov 2020 17:38:06

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered '97.9' F	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:38:06

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered 'Oral (Oral)'	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:38:06

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered empty.	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:38:06

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered '96'	Carlton Griffin (b) (4)	27 Nov 2020 17:38:06



US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'bpm'	System	27 Nov 2020 17:38:06

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered '16'	Carlton Griffin (b) (4)	27 Nov 2020 17:38:06

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'breaths/min'	System	27 Nov 2020 17:38:06

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered '134'	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:38:06

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'mmHg'	System	27 Nov 2020 17:38:06

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered '80'	(b) (4) Carlton Griffin (b) (4) (b) (4)	27 Nov 2020 17:38:06

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'mmHg'	System	27 Nov 2020 17:38:06

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User accepted default value 'Post-Dose (POSTDOSE)'	Carlton Griffin (b) (4) (b) (4)	27 Nov 2020 17:37:18



US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:37:18

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered empty.	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:37:18

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered empty.	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:37:18

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered empty.	System	27 Nov 2020 17:37:18

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered empty.	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:37:18

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered empty.	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:37:18
	(b) (4)	

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered empty.	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:37:18

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered empty.	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:37:18



US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered empty.	System	27 Nov 2020 17:37:18

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered empty.	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:37:18

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered empty.	System	27 Nov 2020 17:37:18

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered empty.	(b) (4) Carlton Griffin (b) (4) (b) (4)	27 Nov 2020 17:37:18

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered empty.	System	27 Nov 2020 17:37:18

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered empty.	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:37:18

US3782198

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered empty.	System	27 Nov 2020 17:37:18

US3782198

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:04:29



US3782198

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:17

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '27 Nov 2020'	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:04:29
	(b) (4)	

US3782198

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	Carlton Griffin (b) (4)	27 Nov 2020 17:41:12

US3782198

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Physician Decision (PHYSICIAN DECISION)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	27 Nov 2020 17:41:12

US3782198

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

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 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'new onset rash of unknown etiology'	Carlton Griffin (b) (4)	27 Nov 2020 17:41:12

US3782198

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered empty.	System	27 Nov 2020 17:41:12

US3782198

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:41:12

US3782198

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:41:12

US3782198

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered empty.	System	27 Nov 2020 17:41:12



US3782198

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:41:12

US3782198

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered empty.	System	27 Nov 2020 17:41:12

US3782198

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered empty.	System	27 Nov 2020 17:41:12

US3782198

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:18:04

US3782198

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '27 Nov 2020'	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:18:04

US3782198

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '11:12' reason for change: Data Entry Error	(b) (4)	
	Carlton Griffin (b) (4)	27 Nov 2020 17:29:15
User entered '10:12'	(b) (4)	
	Carlton Griffin (b) (4)	27 Nov 2020 17:18:04
	(b) (4)	

US3782198

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered '27 Nov 2020 11:12'	System	27 Nov 2020 17:29:15
User entered '27 Nov 2020 10:12'	System	27 Nov 2020 17:18:04

US3782198

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 12 Aug 2021 13:33:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '27 Nov 2020'	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:18:24



**US3782198**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Carlton Griffin (b) (4) (b) (4)	27 Nov 2020 17:18:24

US3782198

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:18:24

US3782198

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:33:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '11:15' reason for change: Data Entry Error	(b) (4)	
	Carlton Griffin (b) (4)	27 Nov 2020 17:29:27
User entered '10:15'	(b) (4)	
	Carlton Griffin (b) (4)	27 Nov 2020 17:18:24
	(b) (4)	

US3782198

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 12 Aug 2021 13:33:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered '27 Nov 2020 11:15'	System	27 Nov 2020 17:29:27
User entered '27 Nov 2020 10:15'	System	27 Nov 2020 17:18:24

US3782198

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:33:17

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Carlton Griffin (b) (4) (b) (4)	27 Nov 2020 17:18:24

US3782198

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 12 Aug 2021 13:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:18:24

**US3782198**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:33:17**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:18:24

**US3782198**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 12 Aug 2021 13:33:17**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered empty.	System	27 Nov 2020 17:18:24



US3782198

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	27 Nov 2020 17:04:04

US3782198

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered '1'	System	27 Nov 2020 17:04:04

US3782198

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	04 Dec 2020 17:44:00

US3782198

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '4 Dec 2020'	(b) (4) Carlton Griffin (b) (4)	04 Dec 2020 17:44:00

US3782198

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	04 Dec 2020 17:44:00

US3782198

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	Carlton Griffin (b) (4)	04 Dec 2020 17:44:00

US3782198

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	04 Dec 2020 17:44:05

**US3782198**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:33:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'I'	System	04 Dec 2020 17:44:05



**US3782198**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:17**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	14 Dec 2020 14:13:56

US3782198

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '13 Dec 2020'	(b) (4) Carlton Griffin (b) (4)	14 Dec 2020 14:13:56

US3782198

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	14 Dec 2020 14:13:56

US3782198

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	Carlton Griffin (b) (4)	14 Dec 2020 14:13:56

US3782198

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	14 Dec 2020 14:14:02

US3782198

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'I'	System	14 Dec 2020 14:14:02

**US3782198**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:17**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	18 Dec 2020 15:48:32

US3782198

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '18 Dec 2020'	(b) (4) Carlton Griffin (b) (4)	18 Dec 2020 15:48:32



US3782198

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	18 Dec 2020 15:48:32

US3782198

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	Carlton Griffin (b) (4)	18 Dec 2020 15:48:32

US3782198

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	18 Dec 2020 15:48:38

US3782198

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered '1'	System	18 Dec 2020 15:48:38

US3782198

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:33:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:32:49

**US3782198**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:33:17**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:32:49

US3782198

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:33:17

[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 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:32:49

US3782198

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:33:17

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'VISIT3'	System	23 Dec 2020 16:32:49



US3782198

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:34:40

US3782198

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:34:40

US3782198

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:34:40

US3782198

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered empty.	System	23 Dec 2020 16:34:40

US3782198

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:34:40

US3782198

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:34:40

**US3782198**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:17**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:34:40

US3782198

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:34:40



**US3782198**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:17**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered empty.	System	23 Dec 2020 16:34:40

US3782198

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:34:40

US3782198

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered empty.	System	23 Dec 2020 16:34:40

US3782198

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:34:40

US3782198

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered empty.	System	23 Dec 2020 16:34:40

US3782198

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:34:40

US3782198

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered empty.	System	23 Dec 2020 16:34:40

US3782198

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28



US3782198

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28

US3782198

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:35:52

US3782198

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:17

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User closed query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	(b) (4)	23 Dec 2020 16:36:05
User entered '23 Dec 2020' reason for change: Data Entry Error	System	23 Dec 2020 16:36:05
User opened query 'Was the physical examination performed is Yes, however Date of examination is missing. Please provide.' (Site from System).	(b) (4), (b) (6)	23 Dec 2020 16:35:52
User entered empty.	(b) (4), (b) (6)	23 Dec 2020 16:35:52

US3782198

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User closed query 'Per GCL Lab Reconciliation: Per GCL, no Immunogenicity sample was received for the Visit 3 Day 57 on 23DEC2020. Please clarify and update if appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Jan 2021 17:46:41
Query 'Per GCL Lab Reconciliation: Per GCL, no Immunogenicity sample was received for the Visit 3 Day 57 on 23DEC2020. Please clarify and update if appropriate. ' answered with 'samples shipping this week.' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	05 Jan 2021 21:06:11
User opened query 'Per GCL Lab Reconciliation: Per GCL, no Immunogenicity sample was received for the Visit 3 Day 57 on 23DEC2020. Please clarify and update if appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 16:22:38
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Dec 2020 16:36:29

US3782198

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:17

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered '23 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:36:29

**US3782198**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:33:17**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered '10:15'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:36:29

US3782198

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered '23 Dec 2020 10:15'	System	23 Dec 2020 16:36:29

US3782198

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:36:37



US3782198

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'I'	System	23 Dec 2020 16:36:37

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 61'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[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 (C656E165-CA95-405A-8514-530A426AE110)', Time: '2020-12-23T10:27:13', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '6eed20e5-d4f7-4d78-8514-89621524eee4' User entered 'No (N)'	System	23 Dec 2020 16:27:34
	System	23 Dec 2020 16:27:34

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Have you been exposed to someone with 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 (C656E165-CA95-405A-8514-530A426AE110)', Time: '2020-12-23T10:27:18', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '6eed20e5-d4f7-4d78-8514-89621524eee4' User entered 'No (N)'	System	23 Dec 2020 16:27:34
	System	23 Dec 2020 16:27:34

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C656E165-CA95-405A-8514-530A426AE110)', Time: '2020-12-23T10:27:29', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '6eed20e5-d4f7-4d78-8514-89621524eee4' User entered '23 Dec 2020 10:27:29'	System	23 Dec 2020 16:27:34
	System	23 Dec 2020 16:27:34

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 68'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[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 (C656E165-CA95-405A-8514-530A426AE110)', Time: '2020-12-27T00:02:25', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '9f04bc22-5faf-4009-b238-fd6818e6cde5' User entered 'No (N)'	System	27 Dec 2020 06:02:51
	System	27 Dec 2020 06:02:51

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

Have you been exposed to someone with 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 (C656E165-CA95-405A-8514-530A426AE110)', Time: '2020-12-27T00:02:41', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '9f04bc22-5faf-4009-b238-fd6818e6cde5' User entered 'No (N)'	System	27 Dec 2020 06:02:51

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C656E165-CA95-405A-8514-530A426AE110)', Time: '2020-12-27T00:02:46', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '9f04bc22-5faf-4009-b238-fd6818e6cde5' User entered '27 Dec 2020 00:02:46'	System	27 Dec 2020 06:02:51
	System	27 Dec 2020 06:02:51

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 75'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[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 (C656E165-CA95-405A-8514-530A426AE110)', Time: '2021-01-03T00:08:10', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '21add5f9-314e-42d3-b922-51835a3a99b1' User entered 'No (N)'	System	03 Jan 2021 06:08:20
	System	03 Jan 2021 06:08:20

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Have you been exposed to someone with 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 (C656E165-CA95-405A-8514-530A426AE110)', Time: '2021-01-03T00:08:13', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '21add5f9-314e-42d3-b922-51835a3a99b1'	System	03 Jan 2021 06:08:20
User entered 'No (N)'	System	03 Jan 2021 06:08:20



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C656E165-CA95-405A-8514-530A426AE110)', Time: '2021-01-03T00:08:17', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '21add5f9-314e-42d3-b922-51835a3a99b1' User entered '03 Jan 2021 00:08:17'	System	03 Jan 2021 06:08:20
	System	03 Jan 2021 06:08:20

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[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 (824EA315-F925-44A5-AC45-20102B3FBF92)', Time: '2021-01-13T08:52:33', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'e658dd21-5cab-4a9a-b4cb-f0a2e62a8432' User entered 'No (N)'	System	13 Jan 2021 14:52:46
	System	13 Jan 2021 14:52:46

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

Have you been exposed to someone with 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 (824EA315-F925-44A5-AC45-20102B3FBF92)', Time: '2021-01-13T08:52:36', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'e658dd21-5cab-4a9a-b4cb-f0a2e62a8432' User entered 'No (N)'	System	13 Jan 2021 14:52:46

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824EA315-F925-44A5-AC45-20102B3F92)', Time: '2021-01-13T08:52:40', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'e658dd21-5cab-4a9a-b4cb-f0a2e62a8432' User entered '13 Jan 2021 08:52:40'	System	13 Jan 2021 14:52:46
	System	13 Jan 2021 14:52:46

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[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 (824EA315-F925-44A5-AC45-20102B3FBF92)', Time: '2021-01-19T12:00:25', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'c5b7f37c-8e25-47ce-b1cd-8e2f37ec1b79'	System	19 Jan 2021 18:00:49
User entered 'No (N)'	System	19 Jan 2021 18:00:49

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Have you been exposed to someone with 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 (824EA315-F925-44A5-AC45-20102B3FBF92)', Time: '2021-01-19T12:00:27', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'c5b7f37c-8e25-47ce-b1cd-8e2f37ec1b79'	System	19 Jan 2021 18:00:49
User entered 'No (N)'	System	19 Jan 2021 18:00:49

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824EA315-F925-44A5-AC45-20102B3FBF92)', Time: '2021-01-19T12:00:30', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'c5b7f37c-8e25-47ce-b1cd-8e2f37ec1b79'	System	19 Jan 2021 18:00:49
User entered '19 Jan 2021 12:00:30'	System	19 Jan 2021 18:00:49

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[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 (824EA315-F925-44A5-AC45-20102B3FBF92)', Time: '2021-01-24T00:08:13', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '4ba1cf2e-63b4-44f7-94f1-2095225c24f2'	System	24 Jan 2021 05:08:23
User entered 'No (N)'	System	24 Jan 2021 05:08:23

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Have you been exposed to someone with 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 (824EA315-F925-44A5-AC45-20102B3FBF92)', Time: '2021-01-24T00:08:17', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '4ba1cf2e-63b4-44f7-94f1-2095225c24f2'	System	24 Jan 2021 05:08:23
User entered 'No (N)'	System	24 Jan 2021 05:08:23

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824EA315-F925-44A5-AC45-20102B3FBF92)', Time: '2021-01-24T00:08:20', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '4ba1cf2e-63b4-44f7-94f1-2095225c24f2' User entered '24 Jan 2021 00:08:20'	System	24 Jan 2021 05:08:23
	System	24 Jan 2021 05:08:23

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[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 (824EA315-F925-44A5-AC45-20102B3FBF92)', Time: '2021-01-31T00:01:14', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '29c13bde-bbf5-4d73-aa77-289f64911b09' User entered 'No (N)'	System	31 Jan 2021 06:01:48
	System	31 Jan 2021 06:01:48

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Have you been exposed to someone with 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 (824EA315-F925-44A5-AC45-20102B3FBF92)', Time: '2021-01-31T00:01:18', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '29c13bde-bbf5-4d73-aa77-289f64911b09' User entered 'No (N)'	System	31 Jan 2021 06:01:48
	System	31 Jan 2021 06:01:48



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (824EA315-F925-44A5-AC45-20102B3F92)', Time: '2021-01-31T00:01:22', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '29c13bde-bbf5-4d73-aa77-289f64911b09' User entered '31 Jan 2021 00:01:22'	System	31 Jan 2021 06:01:48
	System	31 Jan 2021 06:01:48

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[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 (C5BD0314-B942-49DB-9961-D0E3C41D8A14)', Time: '2021-02-10T11:40:11', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '4cf7cd6b-522c-4dbe-b854-53ac052f962a' User entered 'No (N)'	System	10 Feb 2021 17:40:20
	System	10 Feb 2021 17:40:20

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Have you been exposed to someone with 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 (C5BD0314-B942-49DB-9961-D0E3C41D8A14)', Time: '2021-02-10T11:40:13', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '4cf7cd6b-522c-4dbe-b854-53ac052f962a' User entered 'No (N)'	System	10 Feb 2021 17:40:20
	System	10 Feb 2021 17:40:20

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (C5BD0314-B942-49DB-9961-D0E3C41D8A14)', Time: '2021-02-10T11:40:16', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '4cf7cd6b-522c-4dbe-b854-53ac052f962a' User entered '10 Feb 2021 11:40:16'	System	10 Feb 2021 17:40:20
	System	10 Feb 2021 17:40:20

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-02-18T18:49:29', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '33a3e7e6-5d64-46e3-9b19-a3ecbc57f8f5'	System	18 Feb 2021 23:49:38
User entered 'No (N)'	System	18 Feb 2021 23:49:38

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

Have you been exposed to someone with 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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-02-18T18:49:31', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '33a3e7e6-5d64-46e3-9b19-a3ecbc57f8f5' User entered 'No (N)'	System	18 Feb 2021 23:49:38
	System	18 Feb 2021 23:49:38

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-02-18T18:49:35', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '33a3e7e6-5d64-46e3-9b19-a3ecbc57f8f5' User entered '18 Feb 2021 18:49:35'	System	18 Feb 2021 23:49:38
	System	18 Feb 2021 23:49:38

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-02-23T12:00:15', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '564dc36f-e133-4d9b-bc5a-7cfae663d527'	System	23 Feb 2021 18:00:35
User entered 'No (N)'	System	23 Feb 2021 18:00:35

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Have you been exposed to someone with 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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-02-23T12:00:18', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '564dc36f-e133-4d9b-bc5a-7cfae663d527'	System	23 Feb 2021 18:00:35
User entered 'No (N)'	System	23 Feb 2021 18:00:35

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-02-23T12:00:22', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '564dc36f-e133-4d9b-bc5a-7cfae663d527'	System	23 Feb 2021 18:00:35
User entered '23 Feb 2021 12:00:22'	System	23 Feb 2021 18:00:35

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-03-03T13:21:53', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'ab1d9ad9-8198-44ae-94d9-a1cc56247460'	System	03 Mar 2021 19:22:05
User entered 'No (N)'	System	03 Mar 2021 19:22:05

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Have you been exposed to someone with 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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-03-03T13:21:55', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'ab1d9ad9-8198-44ae-94d9-a1cc56247460'	System	03 Mar 2021 19:22:05
User entered 'No (N)'	System	03 Mar 2021 19:22:05



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-03-03T13:21:58', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'ab1d9ad9-8198-44ae-94d9-a1cc56247460'	System	03 Mar 2021 19:22:05
User entered '03 Mar 2021 13:21:58'	System	03 Mar 2021 19:22:05

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-03-07T00:01:38-06:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '04aba857-895c-49cc-b4b7-f1047f1a24c2'	System	07 Mar 2021 06:01:47
User entered 'No (N)'	System	07 Mar 2021 06:01:47

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

Have you been exposed to someone with 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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-03-07T00:01:41-06:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '04aba857-895c-49cc-b4b7-f1047f1a24c2'	System	07 Mar 2021 06:01:47
User entered 'No (N)'	System	07 Mar 2021 06:01:47

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-03-07T00:01:45-06:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '04aba857-895c-49cc-b4b7-f1047f1a24c2'	System	07 Mar 2021 06:01:47
User entered '07 Mar 2021 00:01:45'	System	07 Mar 2021 06:01:47

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-03-14T00:02:21-05:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '0664abd1-4f5c-4d00-aa78-505efb75891a'	System	14 Mar 2021 05:06:09
User entered 'No (N)'	System	14 Mar 2021 05:06:09

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

Have you been exposed to someone with 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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-03-14T00:02:23-05:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '0664abd1-4f5c-4d00-aa78-505efb75891a'	System	14 Mar 2021 05:06:09
User entered 'No (N)'	System	14 Mar 2021 05:06:09

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-03-14T00:02:29-05:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '0664abd1-4f5c-4d00-aa78-505efb75891a' User entered '14 Mar 2021 00:02:29'	System	14 Mar 2021 05:06:09
	System	14 Mar 2021 05:06:09

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-03-21T00:02:11-05:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '5b0178cd-b1bd-4cf9-b6e4-148ab9b5e2ac' User entered 'No (N)'	System	21 Mar 2021 05:02:23
	System	21 Mar 2021 05:02:23

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Have you been exposed to someone with 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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-03-21T00:02:14-05:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '5b0178cd-b1bd-4cf9-b6e4-148ab9b5e2ac' User entered 'No (N)'	System	21 Mar 2021 05:02:23
	System	21 Mar 2021 05:02:23

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-03-21T00:02:16-05:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '5b0178cd-b1bd-4cf9-b6e4-148ab9b5e2ac' User entered '21 Mar 2021 00:02:16'	System	21 Mar 2021 05:02:23
	System	21 Mar 2021 05:02:23

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-03-31T09:53:15-05:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '3c7bb41d-d44e-4c98-8e10-7bd18b352f52'	System	31 Mar 2021 14:53:24
User entered 'No (N)'	System	31 Mar 2021 14:53:24

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

Have you been exposed to someone with 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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-03-31T09:53:17-05:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '3c7bb41d-d44e-4c98-8e10-7bd18b352f52'	System	31 Mar 2021 14:53:24
User entered 'No (N)'	System	31 Mar 2021 14:53:24



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-03-31T09:53:21-05:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '3c7bb41d-d44e-4c98-8e10-7bd18b352f52' User entered '31 Mar 2021 09:53:21'	System	31 Mar 2021 14:53:24
	System	31 Mar 2021 14:53:24

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-04-06T12:00:51-05:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '9bc8a403-4a28-48b0-9e47-f4c8d8b2571c' User entered 'No (N)'	System	06 Apr 2021 17:01:49
	System	06 Apr 2021 17:01:49

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

Have you been exposed to someone with 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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-04-06T12:00:53-05:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '9bc8a403-4a28-48b0-9e47-f4c8d8b2571c'	System	06 Apr 2021 17:01:49
User entered 'No (N)'	System	06 Apr 2021 17:01:49

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-04-06T12:00:57-05:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '9bc8a403-4a28-48b0-9e47-f4c8d8b2571c' User entered '06 Apr 2021 12:00:57'	System	06 Apr 2021 17:01:49
	System	06 Apr 2021 17:01:49

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-04-11T00:08:47-04:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '6340eb81-8a33-474c-975a-a81a46908ac2'	System	11 Apr 2021 04:09:25
User entered 'No (N)'	System	11 Apr 2021 04:09:25

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

Have you been exposed to someone with 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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-04-11T00:08:49-04:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '6340eb81-8a33-474c-975a-a81a46908ac2' User entered 'No (N)'	System	11 Apr 2021 04:09:25
	System	11 Apr 2021 04:09:25

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-04-11T00:08:51-04:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '6340eb81-8a33-474c-975a-a81a46908ac2'	System	11 Apr 2021 04:09:25
User entered '11 Apr 2021 00:08:51'	System	11 Apr 2021 04:09:25

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-04-19T01:46:25-05:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '1d32f2cd-12e2-4601-aae2-57ea0c78acda' User entered 'No (N)'	System	19 Apr 2021 06:46:39
	System	19 Apr 2021 06:46:39

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

Have you been exposed to someone with 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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-04-19T01:46:34-05:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '1d32f2cd-12e2-4601-aae2-57ea0c78acda'	System	19 Apr 2021 06:46:39
User entered 'No (N)'	System	19 Apr 2021 06:46:39

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-04-19T01:46:37-05:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '1d32f2cd-12e2-4601-aae2-57ea0c78acda' User entered '19 Apr 2021 01:46:37'	System	19 Apr 2021 06:46:39
	System	19 Apr 2021 06:46:39

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-04-25T00:03:21-05:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'c650d463-634e-4bf8-9309-e45b438f7f0b' User entered 'No (N)'	System	25 Apr 2021 05:05:29
	System	25 Apr 2021 05:05:29

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

Have you been exposed to someone with 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 (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-04-25T00:03:23-05:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'c650d463-634e-4bf8-9309-e45b438f7f0b'	System	25 Apr 2021 05:05:29
User entered 'No (N)'	System	25 Apr 2021 05:05:29



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-04-25T00:03:26-05:00', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: 'c650d463-634e-4bf8-9309-e45b438f7f0b' User entered '25 Apr 2021 00:03:26'	System	25 Apr 2021 05:05:29
	System	25 Apr 2021 05:05:29

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 13:44:17



**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

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

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 13:44:17



**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 13:44:17



**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 13:44:17



**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 13:44:17



**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '13 Nov 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '17 Nov 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '20 Nov 2022 00:01'	System	20 Nov 2020 13:44:17



**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '24 Nov 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '27 Nov 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '01 Dec 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '04 Dec 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '08 Dec 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 13:44:17



**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '11 Dec 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '15 Dec 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '18 Dec 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '22 Dec 2022 23:59'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '25 Dec 2022 00:01'	System	20 Nov 2020 13:44:17

**US3782198**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 12 Aug 2021 13:33:17**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 13:44:17
Amendment Manager: User entered '29 Dec 2022 23:59'	System	20 Nov 2020 13:44:17



US3782198

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 12 Aug 2021 13:33:17

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)	30 Apr 2021 21:59:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-03-03T13:22:04', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '5ca0fb56-cba6-49d1-9d0f-b1422bf9d4c8'	System	03 Mar 2021 19:22:21
User entered 'Yes (Y)'	System	03 Mar 2021 19:22:21

US3782198

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 12 Aug 2021 13:33:17**

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:59:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-03-03T13:22:08', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '5ca0fb56-cba6-49d1-9d0f-b1422bf9d4c8'	System	03 Mar 2021 19:22:21
User entered 'No (N)'	System	03 Mar 2021 19:22:21

**US3782198**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:59:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A9BFBB7-ECF0-4140-98A0-67E15E2F7F3D)', Time: '2021-03-03T13:22:11', User OID: 'PatientReportedOutcome (US3782198)', ODM File OID: '5ca0fb56-cba6-49d1-9d0f-b1422bf9d4c8' User entered '03 Mar 2021 13:22:11'	System	03 Mar 2021 19:22:21
	System	03 Mar 2021 19:22:21

US3782198

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:24:08

US3782198

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '22 Jan 2021'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:24:08

US3782198

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:24:08

US3782198

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:24:08

US3782198

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Jan 2021 15:24:15



US3782198

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:28:28
User entered 'I'	System	22 Jan 2021 15:24:15

**US3782198**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:17**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:57
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	23 Feb 2021 18:44:23

US3782198

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:57
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered '23 Feb 2021'	Carlton Griffin (b) (4)	23 Feb 2021 18:44:23

**US3782198**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:17**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:57
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered 'Contact Made (CONTACT MADE)'	Carlton Griffin (b) (4)	23 Feb 2021 18:44:23

**US3782198**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:17**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:57
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered empty.	Carlton Griffin (b) (4)	23 Feb 2021 18:44:23

US3782198

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:57
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	23 Feb 2021 18:44:30

**US3782198**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:33:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 15:16:57
User entered 'I'	System	23 Feb 2021 18:44:30

**US3782198**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:17**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:42:12
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	24 Mar 2021 17:01:00



US3782198

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:42:12
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered '24 Mar 2021'	(b) (4) Carlton Griffin (b) (4) (b) (4)	24 Mar 2021 17:01:00

US3782198

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:42:12
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	24 Mar 2021 17:01:00

**US3782198**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:17**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:42:12
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered empty.	(b) (4) Carlton Griffin (b) (4)	24 Mar 2021 17:01:00

US3782198

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:42:12
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	24 Mar 2021 17:01:05

**US3782198**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:33:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:42:12
User entered 'I'	System	24 Mar 2021 17:01:05

**US3782198**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:17**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:19:44

US3782198

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:33
User entered '23 Apr 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:19:44

**US3782198**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:17**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:33
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:19:44



**US3782198**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:17**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:33
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:19:44

US3782198

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:33
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 14:19:51

**US3782198**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:33:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Apr 2021 14:19:51

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:33:17

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	18 Jan 2021 20:13:59

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:33:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '18 Jan 2021'	(b) (4) Carlton Griffin (b) (4)	18 Jan 2021 20:13:59

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:33:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Clinic (Clinic)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	18 Jan 2021 20:13:59

**US3782198**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:33:17**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'UNBLND_DECIDE'	System	18 Jan 2021 20:13:59

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:33:17

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '18 Jan 2021'	(b) (4) Carlton Griffin (b) (4)	18 Jan 2021 20:26:26



**US3782198**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:33:17**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:42:48

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:33:17

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	18 Jan 2021 20:26:26

**US3782198**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:33:17**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 20:42:48

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:33:17

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '18 Jan 2021'	(b) (4) Carlton Griffin (b) (4)	18 Jan 2021 20:26:26

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:33:17

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Carlton Griffin (b) (4)	18 Jan 2021 20:26:26

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:33:17

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 16:23:40
User entered 'mRNA-1273 (mRNA-1273)'	Carlton Griffin (b) (4) (b) (4)	18 Jan 2021 20:26:26

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:33:17

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Not Administered (NA)' reason for change: New Information	(b) (4)	
Amendment Manager: User entered 'Placebo (Placebo)'	Carlton Griffin (b) (4)	21 Jan 2021 17:01:16
User entered 'Placebo (Placebo)'	(b) (4)	
	System	20 Jan 2021 16:23:40
	Carlton Griffin (b) (4)	18 Jan 2021 20:26:26
	(b) (4)	

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 12 Aug 2021 13:33:17

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	18 Jan 2021 20:26:26



**US3782198**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:33:17**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered empty.	System	18 Jan 2021 20:26:26

**US3782198**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 12 Aug 2021 13:33:17**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'I'	System	18 Jan 2021 20:26:26

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 20:45:54
User entered empty.	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	18 Jan 2021 20:45:54
User entered empty.	Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22
	(b) (4)	

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered empty.	System	18 Jan 2021 20:44:22
DataPoint set to visible.	System	18 Jan 2021 20:26:26

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	18 Jan 2021 20:45:54
User entered empty.	Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22
	(b) (4)	

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 20:45:54
User entered empty.	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:17

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered empty.	System	18 Jan 2021 20:44:22
DataPoint set to visible.	System	18 Jan 2021 20:26:26



US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User accepted default value 'Pre-Dose (PREDOSE)'	Trudy Sullivan (b) (4) (b) (4)	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '18 Jan 2021'	Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '14:18'	(b) (4) Trudy Sullivan (b) (4) (b) (4)	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered '18 Jan 2021 14:18'	System	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '98.4' F	Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Oral (Oral)'	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22



US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '92'	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'bpm'	System	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '16'	Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'breaths/min'	System	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '113'	Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'mmHg'	System	18 Jan 2021 20:44:22

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '70'	Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 12 Aug 2021 13:33:17

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'mmHg'	System	18 Jan 2021 20:44:22



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:17

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 20:45:54
User entered empty.	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 12 Aug 2021 13:33:17

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	18 Jan 2021 20:45:54
User entered empty.	Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22
	(b) (4)	

**US3782198**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 12 Aug 2021 13:33:17**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered empty.	System	18 Jan 2021 20:44:22
DataPoint set to visible.	System	18 Jan 2021 20:26:26

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User accepted default value 'Post-Dose (POSTDOSE)'	Trudy Sullivan (b) (4) (b) (4)	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
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	18 Jan 2021 21:02:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Trudy Sullivan (b) (4)	18 Jan 2021 21:02:38
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	18 Jan 2021 20:44:22
	Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '18 Jan 2021' reason for change: Data Entry Error	(b) (4)	
	Trudy Sullivan (b) (4)	18 Jan 2021 21:02:38
User entered empty.	(b) (4)	
	Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '14:59' reason for change: Data Entry Error	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 21:02:38
User entered empty.	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered '18 Jan 2021 14:59'	System	18 Jan 2021 21:02:38
User entered empty.	System	18 Jan 2021 20:44:22



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '97.9' F reason for change: Data Entry Error	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 21:02:38
User entered empty.	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	
	Trudy Sullivan (b) (4)	18 Jan 2021 21:02:38
User entered empty.	(b) (4)	
	Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22
	(b) (4)	

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '84' reason for change: Data Entry Error	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 21:02:38
User entered empty.	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'bpm'	System	18 Jan 2021 21:02:38
User entered empty.	System	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '20' reason for change: Data Entry Error	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 21:02:38
User entered empty.	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22

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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'breaths/min'	System	18 Jan 2021 21:02:38
User entered empty.	System	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '134' reason for change: Data Entry Error	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 21:02:38
User entered empty.	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22



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Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'mmHg'	System	18 Jan 2021 21:02:38
User entered empty.	System	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '77' reason for change: Data Entry Error	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 21:02:38
User entered empty.	(b) (4) Trudy Sullivan (b) (4)	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 12 Aug 2021 13:33:17

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'mmHg'	System	18 Jan 2021 21:02:38
User entered empty.	System	18 Jan 2021 20:44:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	18 Jan 2021 20:26:34

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:17

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '18 Jan 2021'	(b) (4) Carlton Griffin (b) (4)	18 Jan 2021 20:26:34

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	Trudy Sullivan (b) (4)	18 Jan 2021 20:45:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	Trudy Sullivan (b) (4)	18 Jan 2021 20:45:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	Trudy Sullivan (b) (4)	18 Jan 2021 20:45:22



US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'mRNA-1273'	System	18 Jan 2021 20:45:22
DataPoint set to visible.	System	18 Jan 2021 20:26:26

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '18 Jan 2021'	Trudy Sullivan (b) (4)	18 Jan 2021 20:45:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '14:29'	Trudy Sullivan (b) (4)	18 Jan 2021 20:45:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered '18 Jan 2021 14:29'	System	18 Jan 2021 20:45:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Left Arm (LEFT ARM)'	Trudy Sullivan (b) (4)	18 Jan 2021 20:45:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'ONCE'	System	18 Jan 2021 20:45:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 12 Aug 2021 13:33:17

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered 'INTRAMUSCULAR'	System	18 Jan 2021 20:45:22

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	18 Jan 2021 20:14:20



US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '18 Jan 2021'	(b) (4) Carlton Griffin (b) (4)	18 Jan 2021 20:14:20

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '14:10'	(b) (4) Carlton Griffin (b) (4)	18 Jan 2021 20:14:20

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:17

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered '18 Jan 2021 14:10'	System	18 Jan 2021 20:14:20

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	18 Jan 2021 20:14:31

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:33:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '18 Jan 2021'	(b) (4) Carlton Griffin (b) (4)	18 Jan 2021 20:14:31

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 12 Aug 2021 13:33:17

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '14:12'	(b) (4) Carlton Griffin (b) (4) (b) (4)	18 Jan 2021 20:14:31

**US3782198**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 12 Aug 2021 13:33:17**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered '18 Jan 2021 14:12'	System	18 Jan 2021 20:14:31

US3782198

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	18 Jan 2021 20:26:40



**US3782198**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:33:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered '1'	System	18 Jan 2021 20:26:40

**US3782198**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:17**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:56:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 15:05:13

**US3782198**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:17**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:56:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '25 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 15:05:13

US3782198

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 12 Aug 2021 13:33:17

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:56:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:05:13

**US3782198**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 12 Aug 2021 13:33:17**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:56:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:05:13

US3782198

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 12 Aug 2021 13:33:17

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:56:36
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 15:05:22

**US3782198**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:33:17**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:56:36
User entered 'I'	System	25 Jan 2021 15:05:22

**US3782198**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 12 Aug 2021 13:33:17**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:56:36
User entered '1'	System	25 Jan 2021 15:05:22
DataPoint set to visible.	System	25 Jan 2021 15:05:22



**US3782198**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:33:17**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	23 Feb 2021 18:23:37

US3782198

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:33:17

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered '23 Feb 2021'	(b) (4) Carlton Griffin (b) (4)	23 Feb 2021 18:23:37
	(b) (4)	

US3782198

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 12 Aug 2021 13:33:17

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered 'Clinic (Clinic)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	23 Feb 2021 18:23:37

**US3782198**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 12 Aug 2021 13:33:17**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:24
User entered 'OLD29'	System	23 Feb 2021 18:23:37

**US3782198**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:17**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	23 Feb 2021 18:24:23

US3782198

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered empty.	(b) (4) Carlton Griffin (b) (4)	23 Feb 2021 18:24:23

**US3782198**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:17**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered empty.	(b) (4) Carlton Griffin (b) (4)	23 Feb 2021 18:24:23

**US3782198**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:17**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered empty.	System	23 Feb 2021 18:24:23



US3782198

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered empty.	(b) (4) Carlton Griffin (b) (4)	23 Feb 2021 18:24:23

**US3782198**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:17**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered empty.	(b) (4) Carlton Griffin (b) (4)	23 Feb 2021 18:24:23

**US3782198**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:17**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered empty.	(b) (4) Carlton Griffin (b) (4)	23 Feb 2021 18:24:23

US3782198

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered empty.	Carlton Griffin (b) (4)	23 Feb 2021 18:24:23

**US3782198**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:17**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered empty.	System	23 Feb 2021 18:24:23

US3782198

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered empty.	Carlton Griffin (b) (4)	23 Feb 2021 18:24:23

US3782198

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered empty.	System	23 Feb 2021 18:24:23

US3782198

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered empty.	Carlton Griffin (b) (4)	23 Feb 2021 18:24:23



**US3782198**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:17**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered empty.	System	23 Feb 2021 18:24:23

US3782198

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered empty.	Carlton Griffin (b) (4)	23 Feb 2021 18:24:23

**US3782198**

**Folder: OL-D29 (1)**

**Form: Vital Signs**

**Generated On: 12 Aug 2021 13:33:17**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25
User entered empty.	System	23 Feb 2021 18:24:23

US3782198

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25

US3782198

Folder: OL-D29 (1)

Form: Vital Signs

Generated On: 12 Aug 2021 13:33:17

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:25

US3782198

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:17

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	23 Feb 2021 18:31:02

US3782198

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 12 Aug 2021 13:33:17

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered '23 Feb 2021'	Carlton Griffin (b) (4)	23 Feb 2021 18:31:02

US3782198

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:17

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	23 Feb 2021 18:30:22



US3782198

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:17

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered '23 Feb 2021'	(b) (4) Carlton Griffin (b) (4)	23 Feb 2021 18:30:22
	(b) (4)	

US3782198

Folder: OL-D29 (1)

Form: Immunogenicity Assessment

Generated On: 12 Aug 2021 13:33:17

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:24
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
User entered '12:25'	(b) (4) Carlton Griffin (b) (4)	23 Feb 2021 18:30:22

**US3782198**

**Folder: OL-D29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 12 Aug 2021 13:33:17**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:37:24
User entered '23 Feb 2021 12:25'	System	23 Feb 2021 18:30:22

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 12 Aug 2021 13:33:17**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:00:28
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:43:04

US3782198

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:17

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Psoriatic conditions, PT: Psoriasis, LLT: Exacerbation of psoriasis - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 12:45:53
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 12:45:53
	(b) (4)	
Data point term sent to Coder	System	04 Dec 2020 18:29:36
Coding entries removed.	(b) (4), (b) (6)	04 Dec 2020 18:29:31
	(b) (4), (b) (6)	
User entered 'exacerbation psoriasis' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 18:29:31
	(b) (4), (b) (6)	
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Rashes, eruptions and exanthems NEC, PT: Rash papular, LLT: Papular rash - version MedDRA\\23.0.	Coder Import (b) (4)	26 Nov 2020 17:48:16
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Nov 2020 17:48:16
	(b) (4)	
Data point term sent to Coder	System	26 Nov 2020 17:47:32
User entered 'papular rash'	(b) (4), (b) (6)	26 Nov 2020 17:47:26
	(b) (4), (b) (6)	

US3782198

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:17

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	05 Dec 2020 16:33:34
User entered 'No (N)'	(b) (4), (b) (6)	26 Nov 2020 17:47:26

US3782198

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:17

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26



**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '9 Nov 2020'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Nov 2020 17:47:26

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Carlton Griffin (b) (4)	15 Dec 2020 19:45:49
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Nov 2020 17:47:26

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered '5 Dec 2020' reason for change: New Information	Carlton Griffin (b) (4)	15 Dec 2020 19:45:49
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Nov 2020 17:47:26

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Nov 2020 17:47:26

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26



US3782198

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:17

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26

US3782198

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:17

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26

US3782198

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:17

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26



**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26

US3782198

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:17

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26

US3782198

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:17

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26

US3782198

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:17

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User closed query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:50:14
Query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' answered with 'withdrawing product was not specific for the AE; we just did not have another etiology without his PCP evaluation, so it was withdrawn until that was done. Would not have held vaccine if he had this diagnosis within the window' (Site from System).	(b) (4), (b) (6)	05 Dec 2020 16:34:28
User opened query 'Action Taken with Investigational Product is Withdrawn, however Primary reason for Dosing Discontinuation is NOT AE (specify) or SAE (specify). Please review and reconcile.' (Site from System).	System	04 Dec 2020 19:44:45
User entered 'Investigational Product Withdrawn (WITHDRAWN)' reason for change: New Information	Carlton Griffin (b) (4) (b) (4)	27 Nov 2020 17:45:37
User entered 'Dose Delayed (DOSE DELAYED)'	(b) (4), (b) (6)	26 Nov 2020 17:47:26

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26

US3782198

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:17

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'I'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26



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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:17

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Carlton Griffin (b) (4)	15 Dec 2020 19:45:49
	(b) (4)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	26 Nov 2020 17:47:26

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:47:26

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:33:37

US3782198

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:17

[Narrative](#)

Audit	User	Time (GMT)
User entered 'PREVIOUSLY SPOKE TO PARTICIPANT ON 20NOV2020 AND HE REPORTED THE RASH AS RED, SCATTERED, NON-PRURITIC RAISED BUMPS DISPERSED ON HIS BODY. PARTICIPANT REPORTS RASH BEGAN ON 09NOV2020 WITH 1-2 PAPULES AND SLOWLY DEVELOPED ON ALL PARTS OF HIS BODY (EXCEPT FACE, HANDS, AND FEET). REVIEWED WITH DR KALAMS ON 20NOV2020 AND HE URGED PARTICIPANT TO FOLLOW-UP WITH HIS PCP. SCHEDULED DR KALAMS TO SEE PARTICIPANT 23NOV2020 BEFORE PROCEEDING WITH VISIT 2. NOTED ON PHYSICAL EXAM SCATTERED, RED, NON-URTICARIAL PAPULES (WIDESPREAD WITH ~14 SCATTERED ON EACH EXTREMITY, ~20 ON TORSO, ~20 ON BACK, A FEW IN GROIN AREA AND PENIS). PARTICIPANT REPORTS THEY ARE NON-PAINFUL, NON-PRURITIC AND SOMEWHAT IMPROVED (HE DESCRIBES AS LESS RAISED) AFTER HE TREATED RASH OVER THE WEEKEND WITH CLOBETASOL CREAM. THE CLOBETASOL WAS ORIGINALLY PRESCRIBED FOR HIS PSORIASIS LAST YEAR. NOTE PARTICIPANT STATES THIS RASH IS DIFFERENT FROM HIS PSORIASIS AS IT IS NOT SCALING OR DRY.  PARTICIPANT DENIES ANY OTHER MEDICATIONS (SEE CON MED LOG) OR SYMPTOMS. HIS PARTNER IS HIV POSITIVE BUT WITH AN UNDETECTABLE VIRAL LOAD. THEY OCCASIONALLY HAVE OTHER PARTNERS BUT LAST TIME WAS ~ ONE YEAR AGO.  DR KALAMS STATES THIS IS NOT VACCINE RELATED BUT REQUESTED WE HOLD V2 UNTIL PARTICIPANT CAN BE FURTHER EVALUATED BY HIS PCP OR HEALTH DEPARTMENT. GAVE PARTICIPANT CONTACT INFORMATION FOR LOCAL HEALTH DEPARTMENT AND HE STATES HE	Carlton Griffin (b) (4) (b) (4)	27 Nov 2020 17:45:37

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 12 Aug 2021 13:33:17

[Narrative](#)

Audit	User	Time (GMT)
WILL FOLLOW-UP WITH HD OR PCP.' reason for change: New Information		
User entered 'Participant seen 23NOV2020 for v 2 but decided to postpone visit due to new onset rash off unknown etiology with no medical evaluation by PCP. Previously spoke to participant on 20NOV2020 and he reported the rash as red, scattered, non-pruritic raised bumps dispersed on his body. Participant reports rash began on 09NOV2020 with 1-2 papules and slowly developed on all parts of his body (except face, hands, and feet). Reviewed with Dr Kalams on 20NOV2020 and he urged participant to follow-up with his PCP. Scheduled Dr Kalams to see participant 23NOV2020 before proceeding with visit 2. Noted on physical exam scattered, red, non-urticarial papules (widespread with ~14 scattered on each extremity, ~20 on torso, ~20 on back, a few in groin area and penis). Participant reports they are non-painful, non-pruritic and somewhat improved (he describes as less raised) after her treated rash over the weekend with clobetasol cream. The clobetasol was originally prescribed for his psoriasis last year. Note participant states this rash is different from his psoriasis as it is not scaling or dry. Participant denies any other medications (see con med log) or symptoms. His partner is HIV positive but with an undetectable viral load. They occasionally have other partners but last time was ~ one year ago. Dr Kalams states this is not vaccine related but requested we hold v2 until participant can be further evaluated by his PCP or Health Department. Gave participant contact information for local Health Department and he states he will follow-up with HD or PCP.'	(b) (4), (b) (6)	26 Nov 2020 17:47:26

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Nov 2020 17:47:26

**US3782198**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Dec 2020 16:33:34
User entered '0'	System	26 Nov 2020 17:47:26



US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 12 Aug 2021 13:33:17

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 16:00:28
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 16:19:00
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'response was in error' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	23 Mar 2021 19:00:01
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:54:15
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:36:22

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
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.	(b) (4) Coder Import (b) (4) (b) (4)	23 Oct 2020 19:38:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:38:40
Data point term sent to Coder	System	23 Oct 2020 19:37:23
User entered 'ibuprofen'	Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:37:03

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	23 Oct 2020 19:37:03
	(b) (4)	

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:33:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'occasional back pain'	Carlton Griffin (b) (4)	23 Oct 2020 19:37:03
	(b) (4)	

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User closed query 'Per DM CLR: Please ensure to enter in a separate logline per change in dose. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Jan 2021 16:10:54
Query 'Per DM CLR: Please ensure to enter in a separate logline per change in dose. Update eCRF as appropriate. ' answered with 'updated' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	06 Jan 2021 19:54:26
User entered '800' reason for change: Data Entry Error	Carlton Griffin (b) (4) (b) (4)	06 Jan 2021 19:54:21
User opened query 'Per DM CLR: Please ensure to enter in a separate logline per change in dose. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 11:49:33
User entered '200-800'	Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:37:03

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:33:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	23 Oct 2020 19:37:03
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:33:17**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:33:37
User entered empty.	Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:37:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:33:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'as needed (PRN)'	Carlton Griffin (b) (4)	23 Oct 2020 19:37:03
	(b) (4)	



US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:33:17**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:33:37
User entered empty.	Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:37:03

**US3782198**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'Oral (ORAL)'	Carlton Griffin (b) (4)	23 Oct 2020 19:37:03
	(b) (4)	

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:33:17

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:33:37
User entered empty.	Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:37:03

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'UN UNK 2006'	Carlton Griffin (b) (4)	23 Oct 2020 19:37:03
	(b) (4)	

**US3782198**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	23 Oct 2020 19:37:03
	(b) (4)	

**US3782198**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	23 Oct 2020 19:37:03
	(b) (4)	

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 12 Aug 2021 13:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	23 Oct 2020 19:37:03
	(b) (4)	

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	23 Oct 2020 19:37:03
	(b) (4)	



US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:37:03

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:37:03

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 12 Aug 2021 13:33:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Oct 2020 19:37:03

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: PENICILLINS WITH EXTENDED SPECTRUM, PRODUCT: AMOXICILLIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Oct 2020 19:39:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Oct 2020 19:39:42
Data point term sent to Coder	System	23 Oct 2020 19:38:24
User entered 'amoxicillin'	Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:37:37

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	23 Oct 2020 19:37:37
	(b) (4)	

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'strep pharyngitis'	Carlton Griffin (b) (4)	23 Oct 2020 19:37:37
	(b) (4)	

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered '500'	Carlton Griffin (b) (4)	23 Oct 2020 19:37:37
	(b) (4)	

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	23 Oct 2020 19:37:37
	(b) (4)	



US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:33:17**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:33:37
User entered empty.	Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:37:37

**US3782198**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:33:17**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'twice daily (BID)'	Carlton Griffin (b) (4)	23 Oct 2020 19:37:37
	(b) (4)	

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:33:17**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:33:37
User entered empty.	Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:37:37

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:17

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'Oral (ORAL)'	Carlton Griffin (b) (4)	23 Oct 2020 19:37:37
	(b) (4)	

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:33:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:33:37
User entered empty.	Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:37:37

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered '17 Oct 2020'	Carlton Griffin (b) (4)	23 Oct 2020 19:37:37
	(b) (4)	

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	23 Oct 2020 19:37:37
	(b) (4)	

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:48:28
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:37:37



US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 12 Aug 2021 13:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '26 Oct 2020' reason for change: New Information	(b) (4) (b) (4), (b) (6)	20 Nov 2020 17:48:28
User entered empty.	Carlton Griffin (b) (4) (b) (4)	23 Oct 2020 19:37:37

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:33:17**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	23 Oct 2020 19:37:37
	(b) (4)	

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:33:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Oct 2020 19:37:37

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:33:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Oct 2020 19:37:37

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 12 Aug 2021 13:33:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Oct 2020 19:37:37

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, VERY POTENT (GROUP IV), PRODUCT: CLOBETASOL PROPIONATE, PRODUCTSYNONYM: CLOBETASOL 0.05% - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Dec 2020 18:37:46
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 Dec 2020 18:37:46
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	04 Dec 2020 18:31:37 04 Dec 2020 18:30:46
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, VERY POTENT (GROUP IV), PRODUCT: CLOBETASOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Nov 2020 05:24:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Nov 2020 05:24:01
Data point term sent to Coder User entered 'Clobetasol cream 0.05%'	System (b) (4), (b) (6)	26 Nov 2020 17:43:31 26 Nov 2020 17:42:39

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:42:39

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:33:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'exacerbation psoriasis' reason for change: New Information	(b) (4), (b) (6)	04 Dec 2020 18:30:46
User entered 'papular rash'	(b) (4), (b) (6)	26 Nov 2020 17:42:39



US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '1'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:42:39

**US3782198**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:33:17**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:42:39

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:33:17**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'application'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:42:39

**US3782198**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:33:17**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:42:39

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:33:17**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:42:39

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:33:17**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Topical (TOPICAL)'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:42:39

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:33:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:42:39

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '20 Nov 2020'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:42:39



**US3782198**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:33:17**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:42:39

**US3782198**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:33:17**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:42:39

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Nov 2020 17:42:39

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 12 Aug 2021 13:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	26 Nov 2020 17:42:52
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	26 Nov 2020 17:42:52
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	26 Nov 2020 17:42:52
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Nov 2020 17:42:39
User entered empty.	(b) (4), (b) (6)	26 Nov 2020 17:42:39

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:33:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Nov 2020 17:42:39

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:33:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Nov 2020 17:42:39

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 12 Aug 2021 13:33:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Nov 2020 17:42:39

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: AMINOALKYL ETHERS, PRODUCT: DIPHENHYDRAMINE HYDROCHLORIDE, PRODUCTSYNONYM: BENADRYL [DIPHENHYDRAMINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Dec 2020 18:00:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 18:00:49
Data point term sent to Coder	System	04 Dec 2020 19:07:08
User entered 'Benadryl'	(b) (4), (b) (6)	04 Dec 2020 19:06:31



US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:06:31

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:33:17**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'exacerbation psoriasis'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:06:31

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:33:17**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '25'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:06:31

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:33:17**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:06:31

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:17

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:06:31

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:06:31

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:33:17**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:06:31

**US3782198**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:33:17**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:06:31



US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:33:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:06:31

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '26 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:06:31

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:33:17**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:06:31

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:06:31

**US3782198**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:33:17**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '2 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:06:31

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 12 Aug 2021 13:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:06:31

**US3782198**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:33:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 19:06:31

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:33:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 19:06:31



US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 12 Aug 2021 13:33:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 19:06:31

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE, PRODUCTSYNONYM: ROCEPHIN [CEFTRIAXONE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	11 Dec 2020 13:06:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 13:06:49
Data point term sent to Coder	System	04 Dec 2020 19:08:08
User entered 'rocephin'	(b) (4), (b) (6)	04 Dec 2020 19:07:35

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:07:35

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:33:17**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'exacerbation psoriasis'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:07:35

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '2'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:07:35

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:33:17**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:07:35

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:33:17**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'gram'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:07:35

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:33:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:07:35



US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:07:35

**US3782198**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:33:17**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:07:35

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:33:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:07:35

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 12 Aug 2021 13:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '2 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:07:35

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:33:17**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:07:35

**US3782198**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:33:17**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:07:35

**US3782198**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:33:17**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '2 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:07:35

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:33:17**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:07:35



US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:33:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 19:07:35

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:33:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 19:07:35

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 12 Aug 2021 13:33:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 19:07:35

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIPSORIATICS, ATC: ANTIPSORIATICS FOR TOPICAL USE, ATC: OTHER ANTIPSORIATICS FOR TOPICAL USE, PRODUCT: BETAMETHASONE DIPROPIONATE;CALCIPOTRIOL MONOHYDRATE, PRODUCTSYNONYM: ENSTILAR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Dec 2020 08:08:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 08:08:54
Data point term sent to Coder	System	04 Dec 2020 19:09:09
User entered 'enstilar foam'	(b) (4), (b) (6)	04 Dec 2020 19:08:41

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:08:41

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:33:17**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'exacerbation proriasis'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:08:41

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:33:17**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '1'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:08:41

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:33:17**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:08:41



US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:33:17**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'application'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:08:41

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:33:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:08:41

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:33:17**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:08:41

**US3782198**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:33:17**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Topical (TOPICAL)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:08:41

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:33:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:08:41

**US3782198**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:33:17**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '2 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:08:41

**US3782198**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:33:17**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:08:41

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Carlton Griffin (b) (4)	18 Dec 2020 15:49:15
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 19:08:41



US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 12 Aug 2021 13:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered '14 Dec 2020' reason for change: New Information	Carlton Griffin (b) (4)	18 Dec 2020 15:49:15
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 19:08:41

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:33:17**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:08:41

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:33:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 19:08:41

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:33:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 19:08:41

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 12 Aug 2021 13:33:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 19:08:41

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:33:17

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, POTENT (GROUP III), PRODUCT: FLUDROXYCORTIDE, PRODUCTSYNONYM: CORDRAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Dec 2020 05:34:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 05:34:51
Data point term sent to Coder	System	04 Dec 2020 19:11:10
User entered 'cordran cream'	(b) (4), (b) (6)	04 Dec 2020 19:11:05

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:11:05

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:33:17**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'exacerbation proriasis'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:11:05



US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:33:17**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '1'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:11:05

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:33:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:11:05

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:33:17**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'application'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:11:05

**US3782198**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:33:17**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:11:05

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:11:05

**US3782198**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:33:17**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Topical (TOPICAL)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:11:05

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:33:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:11:05

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:33:17**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '2 Dec 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:11:05



**US3782198**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:33:17**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:11:05

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:33:17

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:32:18
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 19:11:05

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '19 Dec 2020' reason for change: New Information	(b) (4) (b) (4), (b) (6)	23 Dec 2020 16:32:18
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 19:11:05

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 12 Aug 2021 13:33:17

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 19:11:27
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Dec 2020 19:11:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Dec 2020 19:11:27
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Dec 2020 19:11:05
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 19:11:05

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:33:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 19:11:05

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:33:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 19:11:05

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 12 Aug 2021 13:33:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 19:11:05

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:33:17

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Con Med METHYLPHENIDATE ER was added/changed on 18 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 15:22:58
Query 'Per DM CLR: Con Med METHYLPHENIDATE ER was added/changed on 18 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'not a worsening/exacerbation; had not been currently on treatment but started treatment for his existing level of anxiety per MH form' (Site from DM).	(b) (4), (b) (6)	15 Mar 2021 17:30:45
User opened query 'Per DM CLR: Con Med METHYLPHENIDATE ER was added/changed on 18 JAN 2021. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	14 Mar 2021 03:52:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: METHYLPHENIDATE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Jan 2021 08:01:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	20 Jan 2021 08:01:03
Data point term sent to Coder	System	19 Jan 2021 15:48:44
User entered 'methylphenidate er'	Carlton Griffin (b) (4)	19 Jan 2021 15:48:14

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:33:17

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	19 Jan 2021 15:48:14
	(b) (4)	

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:33:17

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'anxiety'	Carlton Griffin (b) (4)	19 Jan 2021 15:48:14
	(b) (4)	

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:33:17

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered '36'	Carlton Griffin (b) (4)	19 Jan 2021 15:48:14
	(b) (4)	

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:33:17

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	19 Jan 2021 15:48:14
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:33:17**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	19 Jan 2021 15:48:14
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:33:17

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'once daily (QD)'	Carlton Griffin (b) (4)	19 Jan 2021 15:48:14
	(b) (4)	

US3782198

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:33:17

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	19 Jan 2021 15:48:14
	(b) (4)	

**US3782198**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:33:17**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'Oral (ORAL)'	Carlton Griffin (b) (4)	19 Jan 2021 15:48:14
	(b) (4)	



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:33:17**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	19 Jan 2021 15:48:14
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:33:17

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered '18 Jan 2021'	Carlton Griffin (b) (4)	19 Jan 2021 15:48:14
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:33:17

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	19 Jan 2021 15:48:14
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:33:17**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	19 Jan 2021 15:48:14
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 12 Aug 2021 13:33:17

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	19 Jan 2021 15:48:14
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:33:17**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	19 Jan 2021 15:48:14
	(b) (4)	

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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:33:17**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Jan 2021 15:48:14

US3782198

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:33:17**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Jan 2021 15:48:14



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**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 12 Aug 2021 13:33:17**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Jan 2021 15:48:14

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**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 12 Aug 2021 13:33:17**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:23:35
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	21 Feb 2021 21:06:00
	(b) (4)	

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**Folder: End of Study (1)**

**Form: Dosing Discontinuation**

**Generated On: 12 Aug 2021 13:33:17**

[Date of dosing discontinuation \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:21:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered '27 Nov 2020'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:44:45

US3782198

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:33:17

[Primary reason for dosing discontinuation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:21:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User entered 'Physician decision (specify) (PHYSICIAN DECISION)'	(b) (4) (b) (4), (b) (6)	04 Dec 2020 19:44:45

US3782198

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 12 Aug 2021 13:33:17

If reason is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 04:21:56
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:33:37
User closed query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	(b) (4) System	04 Dec 2020 19:45:21
User entered 'physician decision due to rash of unknown etiology and no medical evaluation available to patient by PCP before window closed' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Dec 2020 19:45:21
User opened query 'Primary reason for dosing discontinuation is AE, SAE, Physician Decision, Withdrawal of consent by participant, Protocol deviation, or Other, however specify is missing. Please provide.' (Site from System).	System	04 Dec 2020 19:44:45
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 19:44:45