

US3782100 (Prod: Vanderbilt University Medical Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:43:22

All time stamps listed in this document are displayed in GMT

**US3782100**

**Form: Participant Creation**

**Data signed:** (b) (4) 26 Jan 2021 20:19:50

**Generated On: 10 Jun 2021 09:43:22**

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[Participant ID](#)

US3782100

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

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US3782100

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

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

US3782100

Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Date of Birth (MMM yyyy)	(b) (6) 1944
Age	76
Age Units	YEARS
Age (Derived)	76
Sex	Female <input checked="" type="radio"/> Male <input 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

US3782100

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Date of Informed Consent ( <i>dd MMM yyyy</i> )	27 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input checked="" type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3782100

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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US3782100

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

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Were any significant conditions reported?

Yes ☒

No ☐

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US3782100

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____



US3782100

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Condition	LEG SPASMS
Start date (dd MMM yyyy)	UN JAN 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)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3782100

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Jan 2021 20:19:56

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

US3782100

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Condition	APPENDECOTMY
Start date (dd MMM yyyy)	UN UNK 1970
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1970
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1970
Start Year (derived)	1970
Stop Month and Year (derived)	JAN 1970
Stop Year (derived)	1970

US3782100

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	27 AUG 2020
Time of assessment ( <i>00:00-23:59</i> )	12:35 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 12:35
Height ( <i>xxx.x</i> )	158 cm
Weight ( <i>xxx.x</i> )	52.4 kg
BMI ( <i>xxx.x</i> )	20.99023 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature ( <i>xxx.x</i> )	ND - Not Done
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse ( <i>xxx</i> )	ND - Not Done
Pulse units	BPM
Respiratory Rate ( <i>xxx</i> )	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure ( <i>xxx</i> )	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3782100

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

27 AUG 2020

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

US3782100

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Date of assessment (dd MMM yyyy) 27 AUG 2020

Is the participant of childbearing potential? Yes ☐  
No ☒

If No, what is the reason? Surgically sterile ☒  
Post-menopausal ☐  
Partner medically sterile ☐  
Not reached age of Menarche ☐  
Other ☐

If Partner medically sterile or Other, specify \_\_\_\_\_

If Surgically sterile, date of surgery (dd MMM yyyy) UN SEP 2000

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) \_\_\_\_\_

Date of last menstruation unknown False

US3782100

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

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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

US3782100

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

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



US3782100

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

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

Visit date (dd MMM yyyy)	27 AUG 2020
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT1
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US3782100

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

What was the date of randomization? (dd MMM yyyy) 27 AUG 2020

What was the participant's randomization number? 188331

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 ☒

US3782100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Height	ND - Not Done
Weight	ND - Not Done

US3782100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

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)	27 AUG 2020
Time of assessment (00:00-23:59)	12:35 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 12:35
Temperature (xxx.x)	98.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3782100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

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)	27 AUG 2020
Time of assessment (00:00-23:59)	13:38 (24 HR)
Vital Signs Date and Time (derived)	27 AUG 2020 13:38
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	57 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	139 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3782100

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

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.*

US3782100

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

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) 27 AUG 2020

What was the treatment time? (00:00-23:59) 13:18 (24 HR)

Treatment Date and Time (derived) 27 AUG 2020 13:18

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

US3782100

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	27 AUG 2020
Collection time (00:00-23:59)	12:50 (24 HR)
Collection date and time (derived)	27 AUG 2020 12:50



US3782100

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Collection date (dd MMM yyyy)			27 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:52	27 AUG 2020 12:52
Nasopharyngeal Swab 2	No		

US3782100

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 AUG 2020 13:43

PC Open Date & Time

27 AUG 2020 13:38

PC Close Date & Time

27 AUG 2020 16:08

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

**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 98.6 °F

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

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

PC Time Stamp	27 AUG 2020 19:48
PC Open Date & Time	27 AUG 2020 17:03
PC Close Date & Time	28 AUG 2020 11:59

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:43:22

**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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 16:25

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:43:22

**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

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 16:54

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:43:22

**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

98.2 °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

30 AUG 2020 17:00

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

31 AUG 2020 15:05

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59



US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

01 SEP 2020 17:15

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 17:04

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

**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

27 AUG 2020 13:43

PC Open Date & Time

27 AUG 2020 13:38

PC Close Date & Time

27 AUG 2020 16:08

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

**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

27 AUG 2020 19:49

PC Open Date & Time

27 AUG 2020 17:03

PC Close Date & Time

28 AUG 2020 11:59

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:43:22

**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

28 AUG 2020 16:26

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:43:22

**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

29 AUG 2020 16:54

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:43:22

**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

30 AUG 2020 17:01

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:43:22

**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

31 AUG 2020 15:06

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59



US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:43:22

**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

01 SEP 2020 17:16

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:43:22

**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

02 SEP 2020 17:04

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

**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 ☐

US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 13:44
PC Open Date & Time	27 AUG 2020 13:38
PC Close Date & Time	27 AUG 2020 16:08

US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

**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 ☐

US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

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

No ☒

Yes ☐

PC Time stamp	27 AUG 2020 19:49
PC Open Date & Time	27 AUG 2020 17:03
PC Close Date & Time	28 AUG 2020 11:59

US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:43:22

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 ☒

US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:43:22

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 16:27
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59



US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:43:22

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  
EAB) (1725)

48 of 2103

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 16:55
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:43:22

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

50 of 2103

EAB) (1725)

US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:43:22

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 17:01
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:43:22

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 ☒

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 15:06
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:43:22

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 ☒

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 17:16
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59



US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:43:22

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 ☒

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 17:05
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3782100

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782100

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782100

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:19:51

Generated On: 10 Jun 2021 09:43:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

10 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782100

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:19:51

Generated On: 10 Jun 2021 09:43:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782100

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:19:51

Generated On: 10 Jun 2021 09:43:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782100

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:19:51

Generated On: 10 Jun 2021 09:43:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3782100

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3782100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

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)	24 SEP 2020
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 10:00
Temperature (xxx.x)	98.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	66 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	142 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG

US3782100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	24 SEP 2020
Time of assessment (00:00-23:59)	11:09 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 11:09
Temperature (xxx.x)	98.4 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	61 mmHg
Diastolic Blood Pressure units	MMHG

US3782100

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3782100

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

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) 24 SEP 2020

What was the treatment time? (00:00-23:59) 10:38 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 10:38

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

US3782100

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 SEP 2020

Collection time (00:00-23:59)

10:05 (24 HR)

Collection date and time (derived)

24 SEP 2020 10:05

US3782100

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:07	24 SEP 2020 10:07
Nasopharyngeal Swab 2	No		

US3782100

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

**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

98.4 °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

24 SEP 2020 11:17

PC Open Date & Time

24 SEP 2020 10:58

PC Close Date & Time

24 SEP 2020 13:28

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.0 °F

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

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

PC Time Stamp	24 SEP 2020 20:05
PC Open Date & Time	24 SEP 2020 14:23
PC Close Date & Time	25 SEP 2020 11:59

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 16:37

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:43:22

**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

98.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 17:03

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:43:22

**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

27 SEP 2020 18:07

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 22:15

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 SEP 2020 15:32

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 17:52

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59



US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

**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

24 SEP 2020 11:18

PC Open Date & Time

24 SEP 2020 10:58

PC Close Date & Time

24 SEP 2020 13:28

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

**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

24 SEP 2020 20:06

PC Open Date & Time

24 SEP 2020 14:23

PC Close Date & Time

25 SEP 2020 11:59

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:43:22

**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

25 SEP 2020 16:37

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:43:22

**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 SEP 2020 17:04

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:43:22

**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

27 SEP 2020 18:07

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:43:22

**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

28 SEP 2020 22:15

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:43:22

**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

29 SEP 2020 15:33

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:43:22

**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

30 SEP 2020 17:52

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59



US3782100

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

**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 ☐

US3782100

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 11:18
PC Open Date & Time	24 SEP 2020 10:58
PC Close Date & Time	24 SEP 2020 13:28

US3782100

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

**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 ☐

US3782100

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 20:06
PC Open Date & Time	24 SEP 2020 14:23
PC Close Date & Time	25 SEP 2020 11:59

US3782100

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:43:22

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 ☒

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 16:38
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3782100

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:43:22

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 ☒

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 17:04
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59



US3782100

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:43:22

**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

96 of 2103

EAB) (1725)

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 18:08
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3782100

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:43:22

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

98 of 2103

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 22:16
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3782100

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:43:22

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

100 of 2103

EAB) (1725)

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 15:33
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3782100

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:43:22

**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 ☒

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 17:52
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59



US3782100

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782100

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782100

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782100

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782100

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782100

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782100

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3782100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 OCT 2020
Time of assessment (00:00-23:59)	07:35 (24 HR)
Vital Signs Date and Time (derived)	22 OCT 2020 07:35
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	147 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	73 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	



US3782100

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 OCT 2020

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

US3782100

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 OCT 2020

Collection time (00:00-23:59)

07:40 (24 HR)

Collection date and time (derived)

22 OCT 2020 07:40

US3782100

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 OCT 2020 12:28:34

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3782100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 NOV 2020 15:34:46

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3782100

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 09:54:54

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 89

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 NOV 2020 11:49:16

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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	28 NOV 2020 06:48:51
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59



US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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 <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	05 DEC 2020 07:00:24
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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

12 DEC 2020 07:53:50

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 DEC 2020 07:52:19

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 11:13:07

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 JAN 2021 10:12:46

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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

09 JAN 2021 06:52:35

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 JAN 2021 10:00:27

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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

25 JAN 2021 10:05:35

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59



US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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

01 FEB 2021 12:57:40

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 FEB 2021 10:19:01

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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

13 FEB 2021 01:25:13

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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

20 FEB 2021 19:34:34

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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

28 FEB 2021 17:39:13

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 10:34:19

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 09:34:40

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 MAR 2021 09:09:52

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59



US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 MAR 2021 06:32:11

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 09:23:28

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 APR 2021 08:37:49

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 09:29:58

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 02:28:05

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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"/>

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

05 MAY 2021 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 257

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

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

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

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

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

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

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

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



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Open Date & Time](#)

15 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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 ☐

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

22 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

29 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Open Date & Time](#)

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05 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

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09 JUN 2021 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 292

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

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

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

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

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

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

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

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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 ☐

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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 ☐

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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 ☐



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

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07 JUL 2021 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

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14 JUL 2021 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Open Date & Time](#)

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17 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUL 2021 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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"/>

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

24 JUL 2021 00:01

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[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 348

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

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

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

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

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

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

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

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Open Date & Time](#)

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07 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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11 AUG 2021 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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 ☐

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

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

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2021 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 369

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

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

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

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

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

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

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

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



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Open Date & Time](#)

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28 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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01 SEP 2021 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 376

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

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

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

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

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

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

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

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 383

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

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

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

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

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

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

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

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Open Date & Time](#)

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11 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

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15 SEP 2021 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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 ☐

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Open Date & Time](#)

18 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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 ☐



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 SEP 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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<a href="#">Patient Cloud Open Date &amp; Time</a>	23 OCT 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	27 OCT 2021 23:59
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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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"/>

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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 $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<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"/>



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

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08 DEC 2021 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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 ☐

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 DEC 2021 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 481

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

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

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

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

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

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

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

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



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

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22 DEC 2021 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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"/>

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 DEC 2021 23:59
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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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"/>

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

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05 JAN 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 509

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

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

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

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

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

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

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

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



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

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26 JAN 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 523

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

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

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

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

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

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

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

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

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02 FEB 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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 ☐

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

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09 FEB 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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 ☐



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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"/>

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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23 FEB 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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 ☐

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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02 MAR 2022 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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 ☐

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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05 MAR 2022 00:01

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09 MAR 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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 ☐



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Open Date & Time](#)

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12 MAR 2022 00:01

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16 MAR 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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 ☐

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

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23 MAR 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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 ☐

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Open Date & Time](#)

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26 MAR 2022 00:01

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30 MAR 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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 ☐

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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 ☐



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

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13 APR 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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"/>

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

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20 APR 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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 ☐  
Yes ☐

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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"/>



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

07 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

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18 MAY 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 635

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

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

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

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

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

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

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

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

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25 MAY 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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"/>



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**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 ☐

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

11 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 663

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

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

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

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

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

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

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

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

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22 JUN 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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"/>

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 677

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

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

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

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

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

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

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

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



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

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20 JUL 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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"/>

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 705

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

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

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

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

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

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

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

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



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 712

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Open Date & Time](#)

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06 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 AUG 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

[Patient Cloud Close Date & Time](#)

17 AUG 2022 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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"/>

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

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24 AUG 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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="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"/>



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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

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31 AUG 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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="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"/>

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

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07 SEP 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 754

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

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

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

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

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

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

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

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

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21 SEP 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 761

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

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

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

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

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

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

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

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



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 768

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

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

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

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

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

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

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

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

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05 OCT 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 775

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

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

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

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

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

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

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

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

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

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

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[Patient Cloud Close Date & Time](#)

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19 OCT 2022 23:59

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US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

DAY 789

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

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

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

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

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

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

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

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



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3782100

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:43:22

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

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

[Patient Cloud Close Date & Time](#)

02 NOV 2022 23:59

**US3782100**

**Folder: Cosmetic Injections and Dermal Fillers**

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

**Generated On: 10 Jun 2021 09:43:22**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 17:38:57

US3782100

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782100

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782100

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:19:51

Generated On: 10 Jun 2021 09:43:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782100

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:19:51

Generated On: 10 Jun 2021 09:43:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3782100

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:19:51

Generated On: 10 Jun 2021 09:43:22

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*

US3782100

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:19:51

Generated On: 10 Jun 2021 09:43:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782100

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782100

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782100

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3782100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

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) \_\_\_\_\_

US3782100

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 MAR 2021

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

US3782100

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

16 MAR 2021

Collection time (00:00-23:59)

10:01 (24 HR)

Collection date and time (derived)

16 MAR 2021 10:01



US3782100

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782100

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 21:42:59

Generated On: 10 Jun 2021 09:43:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782100

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 21:42:59

Generated On: 10 Jun 2021 09:43:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3782100**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

Was Contact Attempted? Yes ☐  
No ☐

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

**US3782100**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3782100**

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

**Form: COVID-19 Contact**

**Generated On: 10 Jun 2021 09:43:22**

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

**US3782100**

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

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

**Generated On: 10 Jun 2021 09:43:22**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3782100

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

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:19:51

Generated On: 10 Jun 2021 09:43:22

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

Visit date (dd MMM yyyy)	5 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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US3782100

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Date of updated informed consent ( <i>dd MMM yyyy</i> )	5 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> )	5 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

**US3782100**

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

**Form: Vital Signs - Dosing**

**Data signed:** (b) (4) 26 Jan 2021 20:19:51

**Generated On: 10 Jun 2021 09:43:22**

Height	158.0 cm
Weight	51.2 kg
BMI (xxx.x)	20.50953

US3782100

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Jan 2021 20:19:51

Generated On: 10 Jun 2021 09:43:22

Height	158.0 cm
Weight	51.2 kg
BMI (xxx.x)	20.50953
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)	5 JAN 2021
Time of assessment (00:00-23:59)	09:01 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 09:01
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	137 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3782100

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Jan 2021 20:19:51

Generated On: 10 Jun 2021 09:43:22

Height	158.0 cm
Weight	51.2 kg
BMI (xxx.x)	20.50953
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)	5 JAN 2021
Time of assessment (00:00-23:59)	10:00 (24 HR)
Vital Signs Date and Time (derived)	5 JAN 2021 10:00
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	55 mmHg
Diastolic Blood Pressure units	MMHG

US3782100

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

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:19:51

Generated On: 10 Jun 2021 09:43:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

5 JAN 2021

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

US3782100

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

Form: Exposure

Data signed: (b) (4) 26 Jan 2021 20:19:51

Generated On: 10 Jun 2021 09:43:22

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) 5 JAN 2021

What was the treatment time? (00:00-23:59) 09:28 (24 HR)

Treatment Date and Time (derived) 5 JAN 2021 09:28

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

US3782100

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:19:51

Generated On: 10 Jun 2021 09:43:22

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 JAN 2021

Collection time (00:00-23:59)

08:56 (24 HR)

Collection date and time (derived)

5 JAN 2021 08:56

US3782100

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Jan 2021 20:19:51

Generated On: 10 Jun 2021 09:43:22

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 JAN 2021
Collection time (00:00 - 23:59)	08:58
Collection Date and Time (derived)	5 JAN 2021 08:58



US3782100

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

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:19:51

Generated On: 10 Jun 2021 09:43:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782100

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

12 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782100

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:19:56

Generated On: 10 Jun 2021 09:43:22

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

US3782100

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 19 Feb 2021 23:29:17

Generated On: 10 Jun 2021 09:43:22

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	2 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

US3782100

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 19 Feb 2021 23:29:17

Generated On: 10 Jun 2021 09:43:22

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 FEB 2021
Time of assessment (00:00-23:59)	08:50 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 08:50
Temperature (xxx.x)	97.6 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3782100

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 19 Feb 2021 23:29:17

Generated On: 10 Jun 2021 09:43:22

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	2 FEB 2021
Time of assessment (00:00-23:59)	09:40 (24 HR)
Vital Signs Date and Time (derived)	2 FEB 2021 09:40
Temperature (xxx.x)	97.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3782100

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 19 Feb 2021 23:29:17

Generated On: 10 Jun 2021 09:43:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

2 FEB 2021

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

US3782100

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 19 Feb 2021 23:29:17

Generated On: 10 Jun 2021 09:43:22

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) 2 FEB 2021

What was the treatment time? (00:00-23:59) 09:10 (24 HR)

Treatment Date and Time (derived) 2 FEB 2021 09:10

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



US3782100

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:29:17

Generated On: 10 Jun 2021 09:43:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782100

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:29:17

Generated On: 10 Jun 2021 09:43:22

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782100

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:29:17

Generated On: 10 Jun 2021 09:43:22

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782100

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3782100

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

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) \_\_\_\_\_

US3782100

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 MAR 2021

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

US3782100

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	16 MAR 2021
Collection time (00:00-23:59)	10:01 (24 HR)
Collection date and time (derived)	16 MAR 2021 10:01

US3782100

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Jan 2021 20:19:50

Generated On: 10 Jun 2021 09:43:22

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---



US3782100

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Jan 2021 20:19:50

Generated On: 10 Jun 2021 09:43:22

AEID	USA-US125-2020-MRNA-1273-P30 1000012
Adverse event	SMALL BOWEL OBSTRUCTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 NOV 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	2 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	30 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	04 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

344 of 2103

US3782100

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Jan 2021 20:19:50

Generated On: 10 Jun 2021 09:43:22

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

US3782100

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Jan 2021 20:19:50

Generated On: 10 Jun 2021 09:43:22

---

04DEC2020  
SPOKE TO PARTICIPANT'S  
HUSBAND TODAY.  
29NOV2020 HE STATES  
PARTICIPANT BEGAN  
EXPERIENCING ABDOMINAL  
PAIN.  
30NOV2020 PAIN CONTINUED  
AND THEY WENT TO THE  
EMERGENCY ROOM AT ST.  
THOMAS WEST. PARTICIPANT  
HAD A CT SCAN THAT  
REVEALED A BLOCKAGE IN  
HER LOWER INTESTINE, AND  
SHE WAS ADMITTED THAT  
EVENING.  
01DEC2020 PARTICIPANT'S  
HUSBAND REPORTS NG TUBE  
WAS PLACED.  
02DEC2020 PARTICIPANT'S  
HUSBAND REPORTS SHE  
UNDERWENT SUCCESSFUL  
LAPAROSCOPIC REMOVAL OF  
ADHESIONS (RELATED TO  
PREVIOUS ABDOMINAL  
SURGERY) TO TREAT HER  
SMALL BOWEL OBSTRUCTION.  
CURRENTLY THEY ARE  
AWAITING DISCHARGE AND  
HER DIET IS PROGRESSING TO  
SOLIDS. WE WILL PLAN TO  
OBTAIN A COPY OF HER  
MEDICAL RECORDS POST  
DISCHARGE. ADDED AE/SAE  
AND CON PROCEDURES BUT  
WILL AWAIT MEDICAL  
RECORDS FOR MEDICATION  
DETAILS

---

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

---

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Jan 2021 20:19:51

Generated On: 10 Jun 2021 09:43:22

---

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

Yes ☒

No ☐

---

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

---

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Name of Medication ROSUVASTATIN

Prophylaxis Yes ☐  
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

348 of 2103

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

	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 2015	
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"/>

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Name of Medication BIOTIN

Prophylaxis Yes ☐  
No ☒

Indication GENERAL HEALTH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

350 of 2103

EAB) (1725)

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

	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 2016	
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"/>



US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Name of Medication VITAMIN D

Prophylaxis Yes ☐  
No ☒

Indication GENERAL HEALTH

Dose per administration 2000

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)

352 of 2103

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

	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 2016	
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"/>

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Name of Medication MAGNESIUM

Prophylaxis Yes ☐  
No ☒

Indication LEG SPASMS

Dose per administration 1250

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)

354 of 2103

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

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

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Name of Medication GLUCOSAMINE

Prophylaxis Yes ☐  
No ☒

Indication LEG SPASMS

Dose per administration 1500

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)

356 of 2103

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

358 of 2103

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

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



US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Name of Medication PNEUMOVAX23

Prophylaxis Yes ☒  
No ☐

Indication PNEUMOCOCCAL  
PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

360 of 2103

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input checked="" 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)		17 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Name of Medication ZOFRAN

Prophylaxis Yes ☐  
No ☒

Indication SMALL BOWEL OBSTRUCTION

Dose per administration 8

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)

362 of 2103

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 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)		30 NOV 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"/>

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Name of Medication GENERAL ANESTHESIA

Prophylaxis Yes ☐  
No ☒

Indication SMALL BOWEL OBSTRUCTION

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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)

364 of 2103

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

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

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Name of Medication LOVENOX

Prophylaxis Yes ☒  
No ☐

Indication DEEP VEIN THROMBOSIS  
PROPHYLAXIS

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☒  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

366 of 2103

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	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)	4 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>



US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Name of Medication GENERAL ANESTHESIA

Prophylaxis Yes ☐  
No ☒

Indication NECK LIFT

Dose per administration UNKNOWN

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

If dose unit is Other, specify UNKNOWN

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)

368 of 2103

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" 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)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy) 11 FEB 2021		
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"/>

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Name of Medication CLINDAMCYIN

Prophylaxis Yes ☒  
No ☐

Indication INFECTION PROPHYLAXIS POST  
NECK LIFT

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

370 of 2103

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Name of Medication HYDROCODONE/ACETAMINOP  
HEN

Prophylaxis Yes ☐  
No ☒

Indication POST-OP PAIN NECK LIFT

Dose per administration 7.5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

372 of 2103

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	11 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication POST-OP PAIN NECK LIFT

Dose per administration 1000

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)

374 of 2103

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 15 FEB 2021		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>



US3782100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Jan 2021 20:19:51

Generated On: 10 Jun 2021 09:43:22

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3782100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 09 Apr 2021 01:17:44

Generated On: 10 Jun 2021 09:43:22

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
2 DEC 2020	LAPAROSCOPIC REMOVAL OF ABDOMINAL ADHESIONS	Adverse Event	
11 FEB 2021	NECK LIFT	Other	ELECTIVE COSMETIC

US3782100

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:43:22

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

US3782100

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:43:22

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 ☐

US3782100

Folder: SAE USA-US125-2020-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 26 Jan 2021 20:19:51

Generated On: 10 Jun 2021 09:43:22

SAEID	USA-US125-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2

US3782100

Folder: SAE USA-US125-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Jan 2021 20:19:51

Generated On: 10 Jun 2021 09:43:22

SAEID	USA-US125-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	05/DEC/2020 16:26
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3782100

Folder: SAE USA-US125-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Jan 2021 20:19:51

Generated On: 10 Jun 2021 09:43:22

SAEID	USA-US125-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	SPYROS
Investigator's Last Name	KALAMS
Site Address: Street	1161 21ST AVENUE SOUTH
Site Address: City	NASHVILLE
Site Address: State	
Site Address: Postal Code	37232
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	2
Date of submission (Pre-filled from custom function)	08/DEC/2020 18:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3782100 (Prod: Vanderbilt University Medical Center)



**US3782100**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:43:22**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'US3782100'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:34:43

**US3782100**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:41:15

**US3782100**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:34:44

**US3782100**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[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 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Clinic (Clinic)'	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 17:41:15

**US3782100**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'SCRN'	System	27 Aug 2020 17:41:15

**US3782100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered (b) (6) 1944'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:34:44

**US3782100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:43:22**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '76'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:41:41

**US3782100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:43:22**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'YEARS'	System	27 Aug 2020 17:41:41



**US3782100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:43:22**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered '76'	System	27 Aug 2020 17:45:36

**US3782100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:43:22**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Female (F)' reason for change: Data Entry Error	(b) (4)	
	Amber Massey (b) (4)	03 Sep 2020 01:29:53
User entered 'Male (M)'	(b) (4)	
	Amber Massey (b) (4)	27 Aug 2020 17:41:41
	(b) (4)	

**US3782100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:43:22**

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:41:41

**US3782100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:43:22**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'I'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:41:41

**US3782100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:43:22**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:41:41

**US3782100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:43:22**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:41:41

**US3782100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:43:22**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:41:41

**US3782100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:43:22**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:41:41



**US3782100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:43:22**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:41:41

**US3782100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:43:22**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 17:41:41

**US3782100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:43:22**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:41:41

**US3782100**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:43:22**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:41:41

**US3782100**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '27 Aug 2020'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:45:36

**US3782100**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'Aug 2020'	System	27 Aug 2020 17:45:36

**US3782100**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered '2020'	System	27 Aug 2020 17:45:36

**US3782100**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:43:22**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Amendment 3 (3)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	28 Aug 2020 15:38:33
User entered 'Amendment 2 (2)'	Amber Massey (b) (4) (b) (4)	27 Aug 2020 17:45:36



**US3782100**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:45:36

**US3782100**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:43:22**

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 17:45:36

**US3782100**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:43:22**

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:45:36

**US3782100**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:43:22**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:45:36

**US3782100**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:43:22**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:34:44

**US3782100**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:43:22**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'I'	System	27 Aug 2020 17:45:36

**US3782100**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:41:23

**US3782100**

**Folder: Screening**

**Form: Medical History Summary**

**Generated On: 10 Jun 2021 09:43:22**

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:55:37



US3782100

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:43:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:49:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:49:04
Data point term sent to Coder	System	27 Aug 2020 18:34:34
User entered 'hypercholesterolemia'	Amber Massey (b) (4)	27 Aug 2020 18:34:25

**US3782100**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'un UNK 2015'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:34:25

**US3782100**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:34:25

**US3782100**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:34:25

**US3782100**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:34:25

**US3782100**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:34:25

**US3782100**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'Jan 2015'	System	27 Aug 2020 18:34:25

**US3782100**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered '2015'	System	27 Aug 2020 18:34:25



**US3782100**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered empty.	System	27 Aug 2020 18:34:25

**US3782100**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered empty.	System	27 Aug 2020 18:34:25

US3782100

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:43:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle related signs and symptoms NEC, PT: Muscle spasms, LLT: Leg spasm - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 11:14:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	05 Sep 2020 11:14:42
Data point term sent to Coder	System	27 Aug 2020 18:35:35
User entered 'leg spasms'	Amber Massey (b) (4)	27 Aug 2020 18:34:38

**US3782100**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'un Jan 2020'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:34:38

**US3782100**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 18:34:38

**US3782100**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:34:38

**US3782100**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:34:38

**US3782100**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:34:38



**US3782100**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'Jan 2020'	System	27 Aug 2020 18:34:38

**US3782100**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered '2020'	System	27 Aug 2020 18:34:38

**US3782100**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered empty.	System	27 Aug 2020 18:34:38

**US3782100**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered empty.	System	27 Aug 2020 18:34:38

US3782100

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:43:22

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 14:53:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 14:53:14
Data point term sent to Coder	System	05 Oct 2020 14:52:33
User entered 'HYSTERECTOMY'	Carlton Griffin (b) (4)	05 Oct 2020 14:51:36

**US3782100**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'UN Sep 2000'	Carlton Griffin (b) (4)	05 Oct 2020 14:51:36

**US3782100**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	Carlton Griffin (b) (4)	05 Oct 2020 14:51:36

**US3782100**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:43:22**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	05 Oct 2020 14:51:36



**US3782100**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'UN Sep 2000'	(b) (4) Carlton Griffin (b) (4)	05 Oct 2020 14:51:36

**US3782100**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:43:22**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	Carlton Griffin (b) (4)	05 Oct 2020 14:51:36

**US3782100**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'Sep 2000'	System	05 Oct 2020 14:51:36

**US3782100**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered '2000'	System	05 Oct 2020 14:51:36

**US3782100**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'Sep 2000'	System	05 Oct 2020 14:51:36

**US3782100**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered '2000'	System	05 Oct 2020 14:51:36

US3782100

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:43:22

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendicectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 12:34:38
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Dec 2020 12:34:38
Data point term sent to Coder	System	07 Dec 2020 19:53:20
User entered 'appendecotmy'	(b) (4), (b) (6)	07 Dec 2020 19:52:50

**US3782100**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'un UNK 1970'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:52:50



**US3782100**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 19:52:50

**US3782100**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:43:22**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:52:50

**US3782100**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'un UNK 1970'	(b) (4), (b) (6)	07 Dec 2020 19:52:50

**US3782100**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:43:22**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 19:52:50

**US3782100**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'Jan 1970'	System	07 Dec 2020 19:52:50

**US3782100**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered '1970'	System	07 Dec 2020 19:52:50

**US3782100**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'Jan 1970'	System	07 Dec 2020 19:52:50

**US3782100**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered '1970'	System	07 Dec 2020 19:52:50



**US3782100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:27:12

US3782100

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '27 Aug 2020'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:27:12

**US3782100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '12:35'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:27:12

**US3782100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered '27 Aug 2020 12:35'	System	27 Aug 2020 18:27:12

**US3782100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '158' cm	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:27:12
DataPoint set to visible.	(b) (4) System	27 Aug 2020 17:45:36

**US3782100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '52.4' kg	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:27:12
DataPoint set to visible.	(b) (4) System	27 Aug 2020 17:45:36

**US3782100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
Amendment Manager: User entered '20.99023'	System	17 Sep 2020 00:05:40
User entered '21.0'	System	27 Aug 2020 18:27:12
DataPoint set to visible.	System	27 Aug 2020 17:45:36

**US3782100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'kg/m2'	System	27 Aug 2020 18:27:12
DataPoint set to visible.	System	27 Aug 2020 17:45:36



**US3782100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:27:12

**US3782100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Oral (Oral)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:27:12

**US3782100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:27:12

**US3782100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:27:12

**US3782100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'bpm'	System	27 Aug 2020 18:27:12

**US3782100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:27:12

**US3782100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'breaths/min'	System	27 Aug 2020 18:27:12

**US3782100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:27:12



**US3782100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'mmHg'	System	27 Aug 2020 18:27:12

**US3782100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:27:12

**US3782100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'mmHg'	System	27 Aug 2020 18:27:12

**US3782100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26

**US3782100**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26

**US3782100**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:43:22**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:55:46

**US3782100**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:43:22**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '27 Aug 2020'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:55:46
	(b) (4)	

**US3782100**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:43:22**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '27 Aug 2020'	(b) (4) Amber Massey (b) (4)	03 Sep 2020 01:30:28



**US3782100**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:43:22**

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	03 Sep 2020 01:30:28

US3782100

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:43:22

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 15:38:53
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. answered with 'MH ecrf updated' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	05 Oct 2020 14:50:33
User closed query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	05 Oct 2020 14:50:28
User opened query 'Post-menopausal has not been entered, however date of last menstruation is provided, or Date of last menstruation unknown is checked. Please correct.' (Site from System).	System	05 Oct 2020 14:50:01
User entered 'Surgically sterile (SURGICALLY STERILE)' reason for change: Data Entry Error	Carlton Griffin (b) (4) (b) (4)	05 Oct 2020 14:50:01
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 05:48:48
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Amber Massey (b) (4) (b) (4)	03 Sep 2020 01:30:28

**US3782100**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:43:22**

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) Amber Massey (b) (4)	03 Sep 2020 01:30:28

**US3782100**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:43:22**

**If Surgically sterile, date of surgery (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User closed query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	(b) (4) System	05 Oct 2020 14:50:28
User entered 'UN Sep 2000' reason for change: Data Entry Error	Carlton Griffin (b) (4) (b) (4)	05 Oct 2020 14:50:28
User opened query 'Surgically sterile been entered, however date of surgery is missing. Please provide.' (Site from System).	System	05 Oct 2020 14:50:01
User entered empty.	Amber Massey (b) (4) (b) (4)	03 Sep 2020 01:30:28

**US3782100**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:43:22**

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	(b) (4) Amber Massey (b) (4)	03 Sep 2020 01:30:28

**US3782100**

**Folder: Screening**

**Form: Childbearing Potential**

**Generated On: 10 Jun 2021 09:43:22**

*If Post-menopausal, date of last menstruation (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) Amber Massey (b) (4)	03 Sep 2020 01:30:28

US3782100

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:43:22

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Carlton Griffin (b) (4)	05 Oct 2020 14:50:28
User entered '1'	(b) (4)	
	Amber Massey (b) (4)	03 Sep 2020 01:30:28
	(b) (4)	

**US3782100**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:43:22**

**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 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 17:56:51



**US3782100**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:43:22**

**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 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 17:56:51

US3782100

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:22

**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 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 17:56:51

US3782100

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:22

**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 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	Amber Massey (b) (4)	27 Aug 2020 17:56:51

US3782100

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:22

[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 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:56:51

US3782100

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:22

[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 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	Amber Massey (b) (4)	27 Aug 2020 17:56:51

US3782100

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:22

**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 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	Amber Massey (b) (4)	27 Aug 2020 17:56:51

US3782100

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:22

**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 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 17:56:51

**US3782100**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:43:22**

**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 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 17:56:51



US3782100

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:22

**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 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	Amber Massey (b) (4)	27 Aug 2020 17:56:51

US3782100

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:22

**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 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	Amber Massey (b) (4)	27 Aug 2020 17:56:51

**US3782100**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:43:22**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:56:51

**US3782100**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:56:51

**US3782100**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:43:22**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:56:51

**US3782100**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:56:51

US3782100

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:22

**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 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	Amber Massey (b) (4)	27 Aug 2020 17:56:51

US3782100

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:22

[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 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:56:51



US3782100

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:22

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 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	Amber Massey (b) (4)	27 Aug 2020 17:56:51

US3782100

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:43:22

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'I'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:56:51

**US3782100**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:43:22**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '0'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:56:51

**US3782100**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:56:51

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:57:06

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '27 Aug 2020'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:57:06

US3782100

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:43:22

[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 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Clinic (Clinic)'	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 17:57:06

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'VISIT1'	System	27 Aug 2020 17:57:06



US3782100

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '27 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:54:54

US3782100

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:43:22

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '188331'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:54:54

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:43:22**

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	27 Aug 2020 17:54:54

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:43:22**

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 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 17:57:15

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:43:22**

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 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 17:57:15

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:43:22**

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:57:15

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:43:22**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:57:15

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:43:22**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:57:15



**US3782100**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 10 Jun 2021 09:43:22**

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	24 Sep 2020 16:23:11
Amendment Manager: DataPoint set to visible.	(b) (4) System	19 Sep 2020 08:17:22
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 08:17:21

US3782100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:43:22

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:28:07

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:43:22**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:28:07

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:43:22**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:28:07

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:43:22**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:28:07

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Massey (b) (4)	27 Aug 2020 18:28:07
	(b) (4)	

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:28:07

US3782100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '27 Aug 2020'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:28:07



**US3782100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '12:35'	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 18:28:07

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered '27 Aug 2020 12:35'	System	27 Aug 2020 18:28:07

US3782100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '98.6' F	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:28:07

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Oral (Oral)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:28:07

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:28:07

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '66'	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 18:28:07

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'bpm'	System	27 Aug 2020 18:28:07

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '16'	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 18:28:07



**US3782100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'breaths/min'	System	27 Aug 2020 18:28:07

US3782100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '139'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:28:07

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'mmHg'	System	27 Aug 2020 18:28:07

US3782100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '68'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:28:07

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'mmHg'	System	27 Aug 2020 18:28:07

US3782100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:43:22

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:28:07

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:43:22**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:28:07

US3782100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User accepted default value 'Post-Dose (POSTDOSE)'	Amber Massey (b) (4) (b) (4)	27 Aug 2020 19:19:27



US3782100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 19:19:27

US3782100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '27 Aug 2020'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 19:19:27

US3782100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '13:38'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 19:19:27

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered '27 Aug 2020 13:38'	System	27 Aug 2020 19:19:27

US3782100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '97.6' F	(b) (4) Amber Massey (b) (4)	27 Aug 2020 19:19:27

US3782100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Oral (Oral)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 19:19:27

US3782100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) Amber Massey (b) (4)	27 Aug 2020 19:19:27

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '57'	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 19:19:27



**US3782100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'bpm'	System	27 Aug 2020 19:19:27

US3782100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '16'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 19:19:27

US3782100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'breaths/min'	System	27 Aug 2020 19:19:27

US3782100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '139'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 19:19:27

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'mmHg'	System	27 Aug 2020 19:19:27

US3782100

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '65'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 19:19:27

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'mmHg'	System	27 Aug 2020 19:19:27

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:43:22**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:57:23



**US3782100**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:43:22**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:57:23

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:28:33

US3782100

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:43:22

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:28:33

US3782100

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:43:22

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 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 18:28:33

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'MRNA-1273 OR PLACEBO'	System	27 Aug 2020 18:28:33

US3782100

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:43:22

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '27 Aug 2020'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:28:33

US3782100

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:43:22

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '13:18'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 18:28:33

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered '27 Aug 2020 13:18'	System	27 Aug 2020 18:28:33



US3782100

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:43:22

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Left Arm (LEFT ARM)'	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 18:28:33

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'ONCE'	System	27 Aug 2020 18:28:33

US3782100

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:43:22

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'INTRAMUSCULAR'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:43:22**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:57:34

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:43:22**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '27 Aug 2020'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:57:34

US3782100

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:22

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '12:50'	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 17:57:34

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:43:22**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered '27 Aug 2020 12:50'	System	27 Aug 2020 17:57:34

US3782100

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:43:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '27 Aug 2020'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:58:29



**US3782100**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amber Massey (b) (4)	27 Aug 2020 17:58:29

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:58:29

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '12:52'	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 17:58:29

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered '27 Aug 2020 12:52'	System	27 Aug 2020 17:58:29

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amber Massey (b) (4)	27 Aug 2020 17:58:29

US3782100

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:43:22

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Sep 2020 01:38:02
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Sep 2020 01:38:02
User entered 'No (N)' reason for change: Data Entry Error	Amber Massey (b) (4)	03 Sep 2020 01:38:02
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	03 Sep 2020 01:37:54
User entered empty; reason for change Data Entry Error	System	03 Sep 2020 01:37:54
User entered 'No (N)'	Amber Massey (b) (4)	03 Sep 2020 01:37:54
	(b) (4)	27 Aug 2020 17:58:29

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	27 Aug 2020 17:58:29

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered empty.	System	27 Aug 2020 17:58:29



**US3782100**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	27 Aug 2020 17:58:39

**US3782100**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'I'	System	27 Aug 2020 17:58:39

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T13:42:34', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd1e3621f-c7e7-454b-9719-43f7855a79eb' User entered 'Yes (Y)'	System	27 Aug 2020 18:43:11
	System	27 Aug 2020 18:43:11

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T13:42:52', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd1e3621f-c7e7-454b-9719-43f7855a79eb' User entered '97.6'	System	27 Aug 2020 18:43:11
	System	27 Aug 2020 18:43:11

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T13:42:58', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd1e3621f-c7e7-454b-9719-43f7855a79eb' User entered 'No (N)'	System	27 Aug 2020 18:43:11
	System	27 Aug 2020 18:43:11

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T13:43:06', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd1e3621f-c7e7-454b-9719-43f7855a79eb' User entered '27 Aug 2020 13:43'	System	27 Aug 2020 18:43:11
	System	27 Aug 2020 18:43:11

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '27 Aug 2020 13:38'	System	27 Aug 2020 18:28:33



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '27 Aug 2020 16:08'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T19:48:09', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd2adb2a6-4b01-4bfc-b516-814aa3b0d51d' User entered 'Yes (Y)'	System	28 Aug 2020 00:48:37
	System	28 Aug 2020 00:48:37

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T19:48:19', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd2adb2a6-4b01-4bfc-b516-814aa3b0d51d' User entered '98.6'	System	28 Aug 2020 00:48:37
	System	28 Aug 2020 00:48:37

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T19:48:25', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd2adb2a6-4b01-4bfc-b516-814aa3b0d51d' User entered 'No (N)'	System	28 Aug 2020 00:48:37
	System	28 Aug 2020 00:48:37

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T19:48:33', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd2adb2a6-4b01-4bfc-b516-814aa3b0d51d' User entered '27 Aug 2020 19:48'	System	28 Aug 2020 00:48:37
	System	28 Aug 2020 00:48:37

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '27 Aug 2020 17:03'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 18:28:33



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 2'	System	27 Aug 2020 18:28:33

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:43:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-28T16:25:15', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'aaa71550-dec1-4e67-a90c-a65a65be0ba9' User entered 'Yes (Y)'	System	28 Aug 2020 21:25:40
	System	28 Aug 2020 21:25:40

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:43:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-28T16:25:22', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'aaa71550-dec1-4e67-a90c-a65a65be0ba9' User entered '98.8'	System	28 Aug 2020 21:25:40
	System	28 Aug 2020 21:25:40

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-28T16:25:27', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'aaa71550-dec1-4e67-a90c-a65a65be0ba9' User entered 'No (N)'	System	28 Aug 2020 21:25:40
	System	28 Aug 2020 21:25:40

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-28T16:25:38', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'aaa71550-dec1-4e67-a90c-a65a65be0ba9' User entered '28 Aug 2020 16:25'	System	28 Aug 2020 21:25:40
	System	28 Aug 2020 21:25:40

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 3'	System	27 Aug 2020 18:28:33



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-29T16:53:56', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '0c2a5388-d15e-4d56-922a-b8b79e283c4d' User entered 'Yes (Y)'	System	29 Aug 2020 21:54:17
	System	29 Aug 2020 21:54:17

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:43:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-29T16:54:06', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '0c2a5388-d15e-4d56-922a-b8b79e283c4d' User entered '98.3'	System	29 Aug 2020 21:54:17
	System	29 Aug 2020 21:54:17

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-29T16:53:19', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '0c2a5388-d15e-4d56-922a-b8b79e283c4d'	System	29 Aug 2020 21:54:17
User entered 'No (N)'	System	29 Aug 2020 21:54:17

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-29T16:54:15', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '0c2a5388-d15e-4d56-922a-b8b79e283c4d' User entered '29 Aug 2020 16:54'	System	29 Aug 2020 21:54:17
	System	29 Aug 2020 21:54:17

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 18:28:33

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 4'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-30T17:00:22', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '3224e217-e5d0-42fb-89df-68b31fe01407'	System	30 Aug 2020 22:00:49
User entered 'Yes (Y)'	System	30 Aug 2020 22:00:49



US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:43:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-30T17:00:30', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '3224e217-e5d0-42fb-89df-68b31fe01407' User entered '98.2'	System	30 Aug 2020 22:00:49
	System	30 Aug 2020 22:00:49

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-30T17:00:36', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '3224e217-e5d0-42fb-89df-68b31fe01407'	System	30 Aug 2020 22:00:49
User entered 'No (N)'	System	30 Aug 2020 22:00:49

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-30T17:00:46', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '3224e217-e5d0-42fb-89df-68b31fe01407'	System	30 Aug 2020 22:00:49
User entered '30 Aug 2020 17:00'	System	30 Aug 2020 22:00:49

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 5'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-31T15:05:32', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '9d410e93-7f65-452f-943d-cf7b26d2eefa' User entered 'Yes (Y)'	System	31 Aug 2020 20:05:54
	System	31 Aug 2020 20:05:54

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:43:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-31T15:05:42', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '9d410e93-7f65-452f-943d-cf7b26d2eefa' User entered '97.9'	System	31 Aug 2020 20:05:54
	System	31 Aug 2020 20:05:54



US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-31T15:05:46', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '9d410e93-7f65-452f-943d-cf7b26d2eefa'	System	31 Aug 2020 20:05:54
User entered 'No (N)'	System	31 Aug 2020 20:05:54

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-31T15:05:52', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '9d410e93-7f65-452f-943d-cf7b26d2eefa' User entered '31 Aug 2020 15:05'	System	31 Aug 2020 20:05:54
	System	31 Aug 2020 20:05:54

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 18:28:33

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 6'	System	27 Aug 2020 18:28:33

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:43:22

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-01T17:15:21', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '165805b0-31fc-4507-9f1f-304f76c985ba' User entered 'Yes (Y)'	System	01 Sep 2020 22:15:51
	System	01 Sep 2020 22:15:51

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:43:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-01T17:15:30', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '165805b0-31fc-4507-9f1f-304f76c985ba' User entered '97.9'	System	01 Sep 2020 22:15:51
	System	01 Sep 2020 22:15:51

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-01T17:15:41', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '165805b0-31fc-4507-9f1f-304f76c985ba' User entered 'No (N)'	System	01 Sep 2020 22:15:51
	System	01 Sep 2020 22:15:51



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-01T17:15:46', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '165805b0-31fc-4507-9f1f-304f76c985ba'	System	01 Sep 2020 22:15:51
User entered '01 Sep 2020 17:15'	System	01 Sep 2020 22:15:51

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 7'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-02T17:04:09', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '4b949bc8-fd52-4f9d-a8cc-dd3a61cf12ff' User entered 'Yes (Y)'	System	02 Sep 2020 22:04:26
	System	02 Sep 2020 22:04:26

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:43:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-02T17:04:15', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '4b949bc8-fd52-4f9d-a8cc-dd3a61cf12ff' User entered '98.6'	System	02 Sep 2020 22:04:26
	System	02 Sep 2020 22:04:26

US3782100

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-02T17:04:19', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '4b949bc8-fd52-4f9d-a8cc-dd3a61cf12ff' User entered 'No (N)'	System	02 Sep 2020 22:04:26
	System	02 Sep 2020 22:04:26

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-02T17:04:23', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '4b949bc8-fd52-4f9d-a8cc-dd3a61cf12ff' User entered '02 Sep 2020 17:04'	System	02 Sep 2020 22:04:26
	System	02 Sep 2020 22:04:26



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 18:28:33

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T13:43:16', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'dd61c0aa-1445-4fca-89d5-44cd92adca1b' User entered 'None (1)'	System	27 Aug 2020 18:43:38
	System	27 Aug 2020 18:43:38

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T13:43:20', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'dd61c0aa-1445-4fca-89d5-44cd92adca1b' User entered 'No (N)'	System	27 Aug 2020 18:43:38
	System	27 Aug 2020 18:43:38

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T13:43:24', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'dd61c0aa-1445-4fca-89d5-44cd92adca1b' User entered 'No (N)'	System	27 Aug 2020 18:43:38
	System	27 Aug 2020 18:43:38

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T13:43:32', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'dd61c0aa-1445-4fca-89d5-44cd92adca1b' User entered 'None (1)'	System	27 Aug 2020 18:43:38
	System	27 Aug 2020 18:43:38

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T13:43:37', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'dd61c0aa-1445-4fca-89d5-44cd92adca1b' User entered '27 Aug 2020 13:43'	System	27 Aug 2020 18:43:38
	System	27 Aug 2020 18:43:38



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '27 Aug 2020 13:38'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '27 Aug 2020 16:08'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 18:28:33

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T19:48:43', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '615ddb4d-1369-47df-8a76-d96d4f9bfd19' User entered 'None (1)'	System	28 Aug 2020 00:49:06
	System	28 Aug 2020 00:49:06

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T19:48:47', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '615ddb4d-1369-47df-8a76-d96d4f9bfd19'	System	28 Aug 2020 00:49:06
User entered 'No (N)'	System	28 Aug 2020 00:49:06

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T19:48:51', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '615ddb4d-1369-47df-8a76-d96d4f9bfd19' User entered 'No (N)'	System	28 Aug 2020 00:49:06
	System	28 Aug 2020 00:49:06

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T19:48:57', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '615ddb4d-1369-47df-8a76-d96d4f9bfd19' User entered 'None (1)'	System	28 Aug 2020 00:49:06
	System	28 Aug 2020 00:49:06

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T19:49:02', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '615ddb4d-1369-47df-8a76-d96d4f9bfd19' User entered '27 Aug 2020 19:49'	System	28 Aug 2020 00:49:06
	System	28 Aug 2020 00:49:06



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '27 Aug 2020 17:03'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 2'	System	27 Aug 2020 18:28:33

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-28T16:25:48', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '76058628-21b9-4bb4-be3f-0ca6cf502d4f' User entered 'None (1)'	System	28 Aug 2020 21:26:18
	System	28 Aug 2020 21:26:18

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-28T16:25:53', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '76058628-21b9-4bb4-be3f-0ca6cf502d4f'	System	28 Aug 2020 21:26:18
User entered 'No (N)'	System	28 Aug 2020 21:26:18

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-28T16:25:57', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '76058628-21b9-4bb4-be3f-0ca6cf502d4f' User entered 'No (N)'	System	28 Aug 2020 21:26:18
	System	28 Aug 2020 21:26:18

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-28T16:26:05', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '76058628-21b9-4bb4-be3f-0ca6cf502d4f' User entered 'None (1)'	System	28 Aug 2020 21:26:18
	System	28 Aug 2020 21:26:18

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-28T16:26:14', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '76058628-21b9-4bb4-be3f-0ca6cf502d4f' User entered '28 Aug 2020 16:26'	System	28 Aug 2020 21:26:18
	System	28 Aug 2020 21:26:18



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 3'	System	27 Aug 2020 18:28:33

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-29T16:54:23', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '4f9ef084-febb-4417-88fc-1e6bc8d18923'	System	29 Aug 2020 21:54:43
User entered 'None (1)'	System	29 Aug 2020 21:54:43

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:43:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-29T16:54:28', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '4f9ef084-febb-4417-88fc-1e6bc8d18923'	System	29 Aug 2020 21:54:43
User entered 'No (N)'	System	29 Aug 2020 21:54:43

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-29T16:54:31', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '4f9ef084-febb-4417-88fc-1e6bc8d18923'	System	29 Aug 2020 21:54:43
User entered 'No (N)'	System	29 Aug 2020 21:54:43

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-29T16:54:37', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '4f9ef084-febb-4417-88fc-1e6bc8d18923'	System	29 Aug 2020 21:54:43
User entered 'None (1)'	System	29 Aug 2020 21:54:43

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-29T16:54:41', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '4f9ef084-febb-4417-88fc-1e6bc8d18923' User entered '29 Aug 2020 16:54'	System	29 Aug 2020 21:54:43
	System	29 Aug 2020 21:54:43



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 4'	System	27 Aug 2020 18:28:33

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-30T17:00:52', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '21264a61-baa6-45d4-a2a2-8b7c5f26a4d8' User entered 'None (1)'	System	30 Aug 2020 22:01:12
	System	30 Aug 2020 22:01:12

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-30T17:00:56', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '21264a61-baa6-45d4-a2a2-8b7c5f26a4d8' User entered 'No (N)'	System	30 Aug 2020 22:01:12
	System	30 Aug 2020 22:01:12

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-30T17:01:01', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '21264a61-baa6-45d4-a2a2-8b7c5f26a4d8' User entered 'No (N)'	System	30 Aug 2020 22:01:12
	System	30 Aug 2020 22:01:12

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-30T17:01:06', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '21264a61-baa6-45d4-a2a2-8b7c5f26a4d8'	System	30 Aug 2020 22:01:12
User entered 'None (1)'	System	30 Aug 2020 22:01:12

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-30T17:01:10', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '21264a61-baa6-45d4-a2a2-8b7c5f26a4d8' User entered '30 Aug 2020 17:01'	System	30 Aug 2020 22:01:12
	System	30 Aug 2020 22:01:12



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 5'	System	27 Aug 2020 18:28:33

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-31T15:05:57', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '85b4c242-1acd-4d24-8edd-9b891ea65e3a' User entered 'None (1)'	System	31 Aug 2020 20:06:16
	System	31 Aug 2020 20:06:16

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-31T15:06:01', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '85b4c242-1acd-4d24-8edd-9b891ea65e3a' User entered 'No (N)'	System	31 Aug 2020 20:06:16
	System	31 Aug 2020 20:06:16

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-31T15:06:06', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '85b4c242-1acd-4d24-8edd-9b891ea65e3a' User entered 'No (N)'	System	31 Aug 2020 20:06:16
	System	31 Aug 2020 20:06:16

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-31T15:06:11', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '85b4c242-1acd-4d24-8edd-9b891ea65e3a'	System	31 Aug 2020 20:06:16
User entered 'None (1)'	System	31 Aug 2020 20:06:16

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-31T15:06:15', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '85b4c242-1acd-4d24-8edd-9b891ea65e3a' User entered '31 Aug 2020 15:06'	System	31 Aug 2020 20:06:16
	System	31 Aug 2020 20:06:16



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 6'	System	27 Aug 2020 18:28:33

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-01T17:16:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '1250d683-52ba-438f-9e4d-db708c93c06f' User entered 'None (1)'	System	01 Sep 2020 22:16:20
	System	01 Sep 2020 22:16:20

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:43:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-01T17:16:03', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '1250d683-52ba-438f-9e4d-db708c93c06f' User entered 'No (N)'	System	01 Sep 2020 22:16:20
	System	01 Sep 2020 22:16:20

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-01T17:16:07', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '1250d683-52ba-438f-9e4d-db708c93c06f' User entered 'No (N)'	System	01 Sep 2020 22:16:20
	System	01 Sep 2020 22:16:20

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-01T17:16:11', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '1250d683-52ba-438f-9e4d-db708c93c06f' User entered 'None (1)'	System	01 Sep 2020 22:16:20
	System	01 Sep 2020 22:16:20

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-01T17:16:17', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '1250d683-52ba-438f-9e4d-db708c93c06f' User entered '01 Sep 2020 17:16'	System	01 Sep 2020 22:16:20
	System	01 Sep 2020 22:16:20



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 7'	System	27 Aug 2020 18:28:33

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-02T17:04:28', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'a8d4a9de-3938-4eba-bf23-54a26555d070' User entered 'None (1)'	System	02 Sep 2020 22:04:47
	System	02 Sep 2020 22:04:47

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:43:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-02T17:04:32', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'a8d4a9de-3938-4eba-bf23-54a26555d070' User entered 'No (N)'	System	02 Sep 2020 22:04:47
	System	02 Sep 2020 22:04:47

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-02T17:04:35', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'a8d4a9de-3938-4eba-bf23-54a26555d070' User entered 'No (N)'	System	02 Sep 2020 22:04:47
	System	02 Sep 2020 22:04:47

US3782100

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-02T17:04:38', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'a8d4a9de-3938-4eba-bf23-54a26555d070' User entered 'None (1)'	System	02 Sep 2020 22:04:47
	System	02 Sep 2020 22:04:47

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-02T17:04:45', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'a8d4a9de-3938-4eba-bf23-54a26555d070' User entered '02 Sep 2020 17:04'	System	02 Sep 2020 22:04:47
	System	02 Sep 2020 22:04:47



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T13:43:46', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '9eae9ba7-da2b-4a86-9dab-c4e655d8067a' User entered 'None (0)'	System	27 Aug 2020 18:44:12
	System	27 Aug 2020 18:44:12

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T13:43:49', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '9eae9ba7-da2b-4a86-9dab-c4e655d8067a' User entered 'None (0)'	System	27 Aug 2020 18:44:12
	System	27 Aug 2020 18:44:12

US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T13:43:52', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '9eae9ba7-da2b-4a86-9dab-c4e655d8067a' User entered 'None (0)'	System	27 Aug 2020 18:44:12
	System	27 Aug 2020 18:44:12

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T13:43:56', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '9eae9ba7-da2b-4a86-9dab-c4e655d8067a' User entered 'None (0)'	System	27 Aug 2020 18:44:12
	System	27 Aug 2020 18:44:12

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T13:43:58', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '9eae9ba7-da2b-4a86-9dab-c4e655d8067a' User entered 'None (0)'	System	27 Aug 2020 18:44:12
	System	27 Aug 2020 18:44:12



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T13:44:01', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '9eae9ba7-da2b-4a86-9dab-c4e655d8067a' User entered 'None (0)'	System	27 Aug 2020 18:44:12
	System	27 Aug 2020 18:44:12

US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T13:44:05', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '9eae9ba7-da2b-4a86-9dab-c4e655d8067a' User entered 'No (N)'	System	27 Aug 2020 18:44:12
	System	27 Aug 2020 18:44:12

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T13:44:11', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '9eae9ba7-da2b-4a86-9dab-c4e655d8067a' User entered '27 Aug 2020 13:44'	System	27 Aug 2020 18:44:12
	System	27 Aug 2020 18:44:12

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '27 Aug 2020 13:38'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '27 Aug 2020 16:08'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 1, after vaccination (at home)'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T19:49:09', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7ec49d8e-c7b1-438e-8ba2-25cbf22e2e62' User entered 'None (0)'	System	28 Aug 2020 00:49:38
	System	28 Aug 2020 00:49:38

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T19:49:13', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7ec49d8e-c7b1-438e-8ba2-25cbf22e2e62' User entered 'None (0)'	System	28 Aug 2020 00:49:38
	System	28 Aug 2020 00:49:38



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T19:49:17', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7ec49d8e-c7b1-438e-8ba2-25cbf22e2e62' User entered 'None (0)'	System	28 Aug 2020 00:49:38
	System	28 Aug 2020 00:49:38

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T19:49:20', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7ec49d8e-c7b1-438e-8ba2-25cbf22e2e62' User entered 'None (0)'	System	28 Aug 2020 00:49:38
	System	28 Aug 2020 00:49:38

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T19:49:24', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7ec49d8e-c7b1-438e-8ba2-25cbf22e2e62' User entered 'None (0)'	System	28 Aug 2020 00:49:38
	System	28 Aug 2020 00:49:38

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T19:49:27', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7ec49d8e-c7b1-438e-8ba2-25cbf22e2e62' User entered 'None (0)'	System	28 Aug 2020 00:49:38
	System	28 Aug 2020 00:49:38

US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T19:49:32', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7ec49d8e-c7b1-438e-8ba2-25cbf22e2e62' User entered 'No (N)'	System	28 Aug 2020 00:49:38
	System	28 Aug 2020 00:49:38

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-27T19:49:36', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7ec49d8e-c7b1-438e-8ba2-25cbf22e2e62'	System	28 Aug 2020 00:49:38
User entered '27 Aug 2020 19:49'	System	28 Aug 2020 00:49:38

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '27 Aug 2020 17:03'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '28 Aug 2020 11:59'	System	27 Aug 2020 18:28:33



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 2'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-28T16:26:21', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '85328e6e-6e95-44cd-a25b-75ff98d88f3c' User entered 'None (0)'	System	28 Aug 2020 21:27:09
	System	28 Aug 2020 21:27:09

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-28T16:26:30', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '85328e6e-6e95-44cd-a25b-75ff98d88f3c' User entered 'None (0)'	System	28 Aug 2020 21:27:09
	System	28 Aug 2020 21:27:09

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-28T16:26:37', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '85328e6e-6e95-44cd-a25b-75ff98d88f3c' User entered 'None (0)'	System	28 Aug 2020 21:27:09
	System	28 Aug 2020 21:27:09

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-28T16:26:46', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '85328e6e-6e95-44cd-a25b-75ff98d88f3c' User entered 'None (0)'	System	28 Aug 2020 21:27:09
	System	28 Aug 2020 21:27:09

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-28T16:26:52', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '85328e6e-6e95-44cd-a25b-75ff98d88f3c' User entered 'None (0)'	System	28 Aug 2020 21:27:09
	System	28 Aug 2020 21:27:09

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-28T16:26:55', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '85328e6e-6e95-44cd-a25b-75ff98d88f3c' User entered 'None (0)'	System	28 Aug 2020 21:27:09
	System	28 Aug 2020 21:27:09

US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-28T16:27:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '85328e6e-6e95-44cd-a25b-75ff98d88f3c' User entered 'No (N)'	System	28 Aug 2020 21:27:09
	System	28 Aug 2020 21:27:09



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-28T16:27:04', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '85328e6e-6e95-44cd-a25b-75ff98d88f3c' User entered '28 Aug 2020 16:27'	System	28 Aug 2020 21:27:09
	System	28 Aug 2020 21:27:09

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '28 Aug 2020 12:00'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '29 Aug 2020 11:59'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 3'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-29T16:54:47', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '2913370c-6e02-484c-abc6-28b2e8e363d7' User entered 'None (0)'	System	29 Aug 2020 21:55:25
	System	29 Aug 2020 21:55:25

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-29T16:54:55', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '2913370c-6e02-484c-abc6-28b2e8e363d7' User entered 'None (0)'	System	29 Aug 2020 21:55:25
	System	29 Aug 2020 21:55:25

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-29T16:55:05', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '2913370c-6e02-484c-abc6-28b2e8e363d7' User entered 'None (0)'	System	29 Aug 2020 21:55:25
	System	29 Aug 2020 21:55:25

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-29T16:55:09', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '2913370c-6e02-484c-abc6-28b2e8e363d7' User entered 'None (0)'	System	29 Aug 2020 21:55:25
	System	29 Aug 2020 21:55:25



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-29T16:55:12', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '2913370c-6e02-484c-abc6-28b2e8e363d7' User entered 'None (0)'	System	29 Aug 2020 21:55:25
	System	29 Aug 2020 21:55:25

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-29T16:55:15', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '2913370c-6e02-484c-abc6-28b2e8e363d7' User entered 'None (0)'	System	29 Aug 2020 21:55:25
	System	29 Aug 2020 21:55:25

US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-29T16:55:20', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '2913370c-6e02-484c-abc6-28b2e8e363d7' User entered 'No (N)'	System	29 Aug 2020 21:55:25
	System	29 Aug 2020 21:55:25

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-29T16:55:23', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '2913370c-6e02-484c-abc6-28b2e8e363d7' User entered '29 Aug 2020 16:55'	System	29 Aug 2020 21:55:25
	System	29 Aug 2020 21:55:25

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '29 Aug 2020 12:00'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '30 Aug 2020 11:59'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 4'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-30T17:01:16', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'ef23bf90-5bd4-4283-b552-cb228094d4f0' User entered 'None (0)'	System	30 Aug 2020 22:02:00
	System	30 Aug 2020 22:02:00



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-30T17:01:24', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'ef23bf90-5bd4-4283-b552-cb228094d4f0' User entered 'None (0)'	System	30 Aug 2020 22:02:00
	System	30 Aug 2020 22:02:00

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-30T17:01:33', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'ef23bf90-5bd4-4283-b552-cb228094d4f0' User entered 'None (0)'	System	30 Aug 2020 22:02:00
	System	30 Aug 2020 22:02:00

US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:43:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-30T17:01:40', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'ef23bf90-5bd4-4283-b552-cb228094d4f0' User entered 'None (0)'	System	30 Aug 2020 22:02:00
	System	30 Aug 2020 22:02:00

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-30T17:01:44', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'ef23bf90-5bd4-4283-b552-cb228094d4f0' User entered 'None (0)'	System	30 Aug 2020 22:02:00
	System	30 Aug 2020 22:02:00

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-30T17:01:47', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'ef23bf90-5bd4-4283-b552-cb228094d4f0' User entered 'None (0)'	System	30 Aug 2020 22:02:00
	System	30 Aug 2020 22:02:00

US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-30T17:01:51', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'ef23bf90-5bd4-4283-b552-cb228094d4f0'	System	30 Aug 2020 22:02:00
User entered 'No (N)'	System	30 Aug 2020 22:02:00

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-30T17:01:55', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'ef23bf90-5bd4-4283-b552-cb228094d4f0' User entered '30 Aug 2020 17:01'	System	30 Aug 2020 22:02:00
	System	30 Aug 2020 22:02:00

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '30 Aug 2020 12:00'	System	27 Aug 2020 18:28:33



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '31 Aug 2020 11:59'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 5'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-31T15:06:21', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd72ccbd5-19b0-47d2-ad8b-1f22ce6777d7' User entered 'None (0)'	System	31 Aug 2020 20:06:51
	System	31 Aug 2020 20:06:51

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-31T15:06:24', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd72ccbd5-19b0-47d2-ad8b-1f22ce6777d7' User entered 'None (0)'	System	31 Aug 2020 20:06:51
	System	31 Aug 2020 20:06:51

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-31T15:06:32', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd72ccbd5-19b0-47d2-ad8b-1f22ce6777d7' User entered 'None (0)'	System	31 Aug 2020 20:06:51
	System	31 Aug 2020 20:06:51

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-31T15:06:34', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd72ccbd5-19b0-47d2-ad8b-1f22ce6777d7' User entered 'None (0)'	System	31 Aug 2020 20:06:51
	System	31 Aug 2020 20:06:51

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-31T15:06:37', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd72ccbd5-19b0-47d2-ad8b-1f22ce6777d7' User entered 'None (0)'	System	31 Aug 2020 20:06:51
	System	31 Aug 2020 20:06:51

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-31T15:06:40', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd72ccbd5-19b0-47d2-ad8b-1f22ce6777d7' User entered 'None (0)'	System	31 Aug 2020 20:06:51
	System	31 Aug 2020 20:06:51



US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-31T15:06:43', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd72ccbd5-19b0-47d2-ad8b-1f22ce6777d7' User entered 'No (N)'	System	31 Aug 2020 20:06:51
	System	31 Aug 2020 20:06:51

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-08-31T15:06:48', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd72ccbd5-19b0-47d2-ad8b-1f22ce6777d7' User entered '31 Aug 2020 15:06'	System	31 Aug 2020 20:06:51
	System	31 Aug 2020 20:06:51

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '31 Aug 2020 12:00'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '01 Sep 2020 11:59'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 6'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-01T17:16:22', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '05572a10-9411-4eaf-8c39-344e63e0e94c' User entered 'None (0)'	System	01 Sep 2020 22:16:47
	System	01 Sep 2020 22:16:47

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-01T17:16:25', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '05572a10-9411-4eaf-8c39-344e63e0e94c' User entered 'None (0)'	System	01 Sep 2020 22:16:47
	System	01 Sep 2020 22:16:47

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-01T17:16:28', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '05572a10-9411-4eaf-8c39-344e63e0e94c' User entered 'None (0)'	System	01 Sep 2020 22:16:47
	System	01 Sep 2020 22:16:47



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-01T17:16:31', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '05572a10-9411-4eaf-8c39-344e63e0e94c' User entered 'None (0)'	System	01 Sep 2020 22:16:47
	System	01 Sep 2020 22:16:47

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-01T17:16:34', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '05572a10-9411-4eaf-8c39-344e63e0e94c' User entered 'None (0)'	System	01 Sep 2020 22:16:47
	System	01 Sep 2020 22:16:47

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-01T17:16:36', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '05572a10-9411-4eaf-8c39-344e63e0e94c' User entered 'None (0)'	System	01 Sep 2020 22:16:47
	System	01 Sep 2020 22:16:47

US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-01T17:16:40', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '05572a10-9411-4eaf-8c39-344e63e0e94c' User entered 'No (N)'	System	01 Sep 2020 22:16:47
	System	01 Sep 2020 22:16:47

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-01T17:16:45', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '05572a10-9411-4eaf-8c39-344e63e0e94c' User entered '01 Sep 2020 17:16'	System	01 Sep 2020 22:16:47
	System	01 Sep 2020 22:16:47

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '01 Sep 2020 12:00'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '02 Sep 2020 11:59'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 7'	System	27 Aug 2020 18:28:33



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-02T17:04:49', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '621a9d51-edc0-4ff6-a133-2fe501b9fb63' User entered 'None (0)'	System	02 Sep 2020 22:05:10
	System	02 Sep 2020 22:05:10

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-02T17:04:52', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '621a9d51-edc0-4ff6-a133-2fe501b9fb63' User entered 'None (0)'	System	02 Sep 2020 22:05:10
	System	02 Sep 2020 22:05:10

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-02T17:04:54', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '621a9d51-edc0-4ff6-a133-2fe501b9fb63' User entered 'None (0)'	System	02 Sep 2020 22:05:10
	System	02 Sep 2020 22:05:10

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-02T17:04:56', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '621a9d51-edc0-4ff6-a133-2fe501b9fb63' User entered 'None (0)'	System	02 Sep 2020 22:05:10
	System	02 Sep 2020 22:05:10

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-02T17:04:59', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '621a9d51-edc0-4ff6-a133-2fe501b9fb63' User entered 'None (0)'	System	02 Sep 2020 22:05:10
	System	02 Sep 2020 22:05:10

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-02T17:05:01', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '621a9d51-edc0-4ff6-a133-2fe501b9fb63' User entered 'None (0)'	System	02 Sep 2020 22:05:10
	System	02 Sep 2020 22:05:10

US3782100

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-02T17:05:04', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '621a9d51-edc0-4ff6-a133-2fe501b9fb63'	System	02 Sep 2020 22:05:10
User entered 'No (N)'	System	02 Sep 2020 22:05:10

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-02T17:05:06', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '621a9d51-edc0-4ff6-a133-2fe501b9fb63' User entered '02 Sep 2020 17:05'	System	02 Sep 2020 22:05:10
	System	02 Sep 2020 22:05:10



**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '02 Sep 2020 12:00'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '03 Sep 2020 11:59'	System	27 Aug 2020 18:28:33

**US3782100**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 13:32:00

**US3782100**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '3 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 13:32:00

**US3782100**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 13:32:00

**US3782100**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 13:32:00

**US3782100**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 13:32:06

**US3782100**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'I'	System	03 Sep 2020 13:32:06



**US3782100**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:18

**US3782100**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:18

**US3782100**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:18

**US3782100**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:18

**US3782100**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 16:09:23

**US3782100**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'I'	System	10 Sep 2020 16:09:23

**US3782100**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	17 Sep 2020 16:07:55

**US3782100**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

**Date of Contact or Contact Attempt (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '17 Sep 2020'	(b) (4) Amber Massey (b) (4)	17 Sep 2020 16:07:55



**US3782100**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amber Massey (b) (4)	17 Sep 2020 16:07:55

**US3782100**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	17 Sep 2020 16:07:55

**US3782100**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	17 Sep 2020 16:07:44

**US3782100**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'I'	System	17 Sep 2020 16:07:44

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:34:28

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:34:28

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[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 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:34:28

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'VISIT2'	System	24 Sep 2020 15:34:28



US3782100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	24 Sep 2020 15:44:21

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:44:21

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:44:21

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '10:00'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:44:21

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered '24 Sep 2020 10:00'	System	24 Sep 2020 15:44:21

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '98.8' F	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:44:21

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:44:21

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:44:21



**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '66'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:44:21

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'bpm'	System	24 Sep 2020 15:44:21

US3782100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '16'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:44:21

US3782100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:43:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'breaths/min'	System	24 Sep 2020 15:44:21

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '142'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:44:21

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'mmHg'	System	24 Sep 2020 15:44:21

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '67'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:44:21

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'mmHg'	System	24 Sep 2020 15:44:21



US3782100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User accepted default value 'Post-Dose (POSTDOSE)'	Amy Kerrigan (b) (4) (b) (4)	24 Sep 2020 16:17:54

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Amy Kerrigan (b) (4)	24 Sep 2020 16:17:54

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '24 Sep 2020'	(b) (4) Amy Kerrigan (b) (4)	24 Sep 2020 16:17:54

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '11:09'	(b) (4) Amy Kerrigan (b) (4) (b) (4)	24 Sep 2020 16:17:54

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered '24 Sep 2020 11:09'	System	24 Sep 2020 16:17:54

US3782100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '98.4' F	Amy Kerrigan (b) (4)	24 Sep 2020 16:17:54

US3782100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Oral (Oral)'	(b) (4) Amy Kerrigan (b) (4)	24 Sep 2020 16:17:54

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) Amy Kerrigan (b) (4)	24 Sep 2020 16:17:54



US3782100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '61'	(b) (4) Amy Kerrigan (b) (4)	24 Sep 2020 16:17:54

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'bpm'	System	24 Sep 2020 16:17:54

US3782100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '16'	(b) (4) Amy Kerrigan (b) (4)	24 Sep 2020 16:17:54

US3782100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'breaths/min'	System	24 Sep 2020 16:17:54

US3782100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '126'	(b) (4) Amy Kerrigan (b) (4)	24 Sep 2020 16:17:54

US3782100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'mmHg'	System	24 Sep 2020 16:17:54

US3782100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '61'	(b) (4) Amy Kerrigan (b) (4) (b) (4)	24 Sep 2020 16:17:54

US3782100

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'mmHg'	System	24 Sep 2020 16:17:54



**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:43:22**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:34:40

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:43:22**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:34:40

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:43:14

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:43:14

US3782100

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:43:22

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 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:43:14

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'MRNA-1273 OR PLACEBO'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:43:14

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '10:38'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:43:14



**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered '24 Sep 2020 10:38'	System	24 Sep 2020 15:43:14

US3782100

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:43:22

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:43:14

US3782100

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:43:22

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'ONCE'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'INTRAMUSCULAR'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:43:22**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:35:18

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:43:22**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:35:18

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '10:05'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:35:18

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:43:22**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered '24 Sep 2020 10:05'	System	24 Sep 2020 15:35:18



**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 10 Jun 2021 09:43:22**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:35:41

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	24 Sep 2020 15:35:41

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:35:41

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '10:07'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:35:41

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered '24 Sep 2020 10:07'	System	24 Sep 2020 15:35:41

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	24 Sep 2020 15:35:41

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:35:41

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:35:41



**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered empty.	System	24 Sep 2020 15:35:41

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 15:42:52

**US3782100**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'I'	System	24 Sep 2020 15:42:52

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T11:17:18', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd6479234-fc6a-48ac-a994-1d5eb44cdedf' User entered 'Yes (Y)'	System	24 Sep 2020 16:17:41
	System	24 Sep 2020 16:17:41

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T11:17:29', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd6479234-fc6a-48ac-a994-1d5eb44cdedf' User entered '98.4'	System	24 Sep 2020 16:17:41
	System	24 Sep 2020 16:17:41

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T11:17:35', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd6479234-fc6a-48ac-a994-1d5eb44cdedf' User entered 'No (N)'	System	24 Sep 2020 16:17:41
	System	24 Sep 2020 16:17:41

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T11:17:40', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd6479234-fc6a-48ac-a994-1d5eb44cdedf' User entered '24 Sep 2020 11:17'	System	24 Sep 2020 16:17:41
	System	24 Sep 2020 16:17:41



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '24 Sep 2020 10:58'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '24 Sep 2020 13:28'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T20:05:14', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'de5fd090-db28-4000-80d9-899a82043bcc' User entered 'Yes (Y)'	System	25 Sep 2020 01:05:36
	System	25 Sep 2020 01:05:36

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T20:05:24', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'de5fd090-db28-4000-80d9-899a82043bcc' User entered '97.0'	System	25 Sep 2020 01:05:36
	System	25 Sep 2020 01:05:36

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T20:05:29', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'de5fd090-db28-4000-80d9-899a82043bcc' User entered 'No (N)'	System	25 Sep 2020 01:05:36
	System	25 Sep 2020 01:05:36

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T20:05:33', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'de5fd090-db28-4000-80d9-899a82043bcc' User entered '24 Sep 2020 20:05'	System	25 Sep 2020 01:05:36
	System	25 Sep 2020 01:05:36

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '24 Sep 2020 14:23'	System	24 Sep 2020 15:43:14



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 2'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-25T16:37:01', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '5a6822ba-fa71-4f3f-b195-6ffa496b8b31' User entered 'Yes (Y)'	System	25 Sep 2020 21:37:20
	System	25 Sep 2020 21:37:20

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:43:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-25T16:37:08', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '5a6822ba-fa71-4f3f-b195-6ffa496b8b31' User entered '97.3'	System	25 Sep 2020 21:37:20
	System	25 Sep 2020 21:37:20

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-25T16:37:11', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '5a6822ba-fa71-4f3f-b195-6ffa496b8b31' User entered 'No (N)'	System	25 Sep 2020 21:37:20
	System	25 Sep 2020 21:37:20

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-25T16:37:18', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '5a6822ba-fa71-4f3f-b195-6ffa496b8b31' User entered '25 Sep 2020 16:37'	System	25 Sep 2020 21:37:20
	System	25 Sep 2020 21:37:20

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 15:43:14



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 3'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-26T17:03:32', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'e8b9b219-27cb-47cd-b588-9f9651e1fcdc' User entered 'Yes (Y)'	System	26 Sep 2020 22:03:58
	System	26 Sep 2020 22:03:58

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:43:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-26T17:03:39', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'e8b9b219-27cb-47cd-b588-9f9651e1fcdc' User entered '98.6'	System	26 Sep 2020 22:03:58
	System	26 Sep 2020 22:03:58

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-26T17:03:43', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'e8b9b219-27cb-47cd-b588-9f9651e1fcdc' User entered 'No (N)'	System	26 Sep 2020 22:03:58
	System	26 Sep 2020 22:03:58

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-26T17:03:52', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'e8b9b219-27cb-47cd-b588-9f9651e1fcdc' User entered '26 Sep 2020 17:03'	System	26 Sep 2020 22:03:58
	System	26 Sep 2020 22:03:58

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 15:43:14

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 4'	System	24 Sep 2020 15:43:14



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-27T18:07:17', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'a8a62735-79a2-47d5-bca2-4cce47326ecc' User entered 'Yes (Y)'	System	27 Sep 2020 23:07:41
	System	27 Sep 2020 23:07:41

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:43:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-27T18:07:24', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'a8a62735-79a2-47d5-bca2-4cce47326ecc' User entered '98.4'	System	27 Sep 2020 23:07:41
	System	27 Sep 2020 23:07:41

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-27T18:07:35', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'a8a62735-79a2-47d5-bca2-4cce47326ecc' User entered 'No (N)'	System	27 Sep 2020 23:07:41
	System	27 Sep 2020 23:07:41

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-27T18:07:38', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'a8a62735-79a2-47d5-bca2-4cce47326ecc' User entered '27 Sep 2020 18:07'	System	27 Sep 2020 23:07:41
	System	27 Sep 2020 23:07:41

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 15:43:14

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:43:22

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 5'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-28T22:14:43', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'c8aa1fc9-7daf-413b-8bf9-79e3cbf0dd1c' User entered 'Yes (Y)'	System	29 Sep 2020 03:15:17
	System	29 Sep 2020 03:15:17



US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:43:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-28T22:14:52', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'c8aa1fc9-7daf-413b-8bf9-79e3cbf0dd1c' User entered '97.0'	System	29 Sep 2020 03:15:17
	System	29 Sep 2020 03:15:17

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-28T22:15:11', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'c8aa1fc9-7daf-413b-8bf9-79e3cbf0dd1c'	System	29 Sep 2020 03:15:17
User entered 'No (N)'	System	29 Sep 2020 03:15:17

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-28T22:15:14', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'c8aa1fc9-7daf-413b-8bf9-79e3cbf0dd1c' User entered '28 Sep 2020 22:15'	System	29 Sep 2020 03:15:17
	System	29 Sep 2020 03:15:17

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 6'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-29T15:32:33', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '29a68875-5058-46f5-b3fd-2a28f8dd3434' User entered 'Yes (Y)'	System	29 Sep 2020 20:32:52
	System	29 Sep 2020 20:32:52

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:43:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-29T15:32:40', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '29a68875-5058-46f5-b3fd-2a28f8dd3434' User entered '97.7'	System	29 Sep 2020 20:32:52
	System	29 Sep 2020 20:32:52



US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-29T15:32:47', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '29a68875-5058-46f5-b3fd-2a28f8dd3434'	System	29 Sep 2020 20:32:52
User entered 'No (N)'	System	29 Sep 2020 20:32:52

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-29T15:32:51', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '29a68875-5058-46f5-b3fd-2a28f8dd3434' User entered '29 Sep 2020 15:32'	System	29 Sep 2020 20:32:52
	System	29 Sep 2020 20:32:52

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 7'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

**Was TEMPERATURE taken?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-30T17:51:51', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '4a440372-4ac5-44b8-8d47-27c2bf7cf8bd' User entered 'Yes (Y)'	System	30 Sep 2020 22:52:09
	System	30 Sep 2020 22:52:09

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:43:22

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-30T17:51:59', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '4a440372-4ac5-44b8-8d47-27c2bf7cf8bd' User entered '98.3'	System	30 Sep 2020 22:52:09
	System	30 Sep 2020 22:52:09

US3782100

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-30T17:52:02', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '4a440372-4ac5-44b8-8d47-27c2bf7cf8bd'	System	30 Sep 2020 22:52:09
User entered 'No (N)'	System	30 Sep 2020 22:52:09



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-30T17:52:05', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '4a440372-4ac5-44b8-8d47-27c2bf7cf8bd' User entered '30 Sep 2020 17:52'	System	30 Sep 2020 22:52:09
	System	30 Sep 2020 22:52:09

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 15:43:14

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T11:17:45', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '1fce42ae-8a22-4e5e-a42e-f1bfecf280e6'	System	24 Sep 2020 16:18:08
User entered 'None (1)'	System	24 Sep 2020 16:18:08

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T11:17:50', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '1fce42ae-8a22-4e5e-a42e-f1bfecf280e6'	System	24 Sep 2020 16:18:08
User entered 'No (N)'	System	24 Sep 2020 16:18:08

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T11:17:53', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '1fce42ae-8a22-4e5e-a42e-f1bfecf280e6' User entered 'No (N)'	System	24 Sep 2020 16:18:08
	System	24 Sep 2020 16:18:08

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T11:18:01', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '1fce42ae-8a22-4e5e-a42e-f1bfecf280e6'	System	24 Sep 2020 16:18:08
User entered 'None (1)'	System	24 Sep 2020 16:18:08



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T11:18:04', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '1fce42ae-8a22-4e5e-a42e-f1bfecf280e6'	System	24 Sep 2020 16:18:08
User entered '24 Sep 2020 11:18'	System	24 Sep 2020 16:18:08

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '24 Sep 2020 10:58'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '24 Sep 2020 13:28'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 15:43:14

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T20:05:41', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '083eded8-5b6a-428c-a31d-85c9e1356b6f' User entered 'None (1)'	System	25 Sep 2020 01:06:25
	System	25 Sep 2020 01:06:25

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T20:05:44', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '083eded8-5b6a-428c-a31d-85c9e1356b6f' User entered 'No (N)'	System	25 Sep 2020 01:06:25
	System	25 Sep 2020 01:06:25

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T20:05:48', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '083eded8-5b6a-428c-a31d-85c9e1356b6f' User entered 'No (N)'	System	25 Sep 2020 01:06:25
	System	25 Sep 2020 01:06:25

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T20:06:01', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '083eded8-5b6a-428c-a31d-85c9e1356b6f' User entered 'None (1)'	System	25 Sep 2020 01:06:25
	System	25 Sep 2020 01:06:25



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T20:06:23', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '083eded8-5b6a-428c-a31d-85c9e1356b6f' User entered '24 Sep 2020 20:06'	System	25 Sep 2020 01:06:25
	System	25 Sep 2020 01:06:25

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '24 Sep 2020 14:23'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 2'	System	24 Sep 2020 15:43:14

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-25T16:37:32', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '41ed7967-bf13-4066-80eb-5cd3250b1010'	System	25 Sep 2020 21:37:49
User entered 'None (1)'	System	25 Sep 2020 21:37:49

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:43:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-25T16:37:35', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '41ed7967-bf13-4066-80eb-5cd3250b1010'	System	25 Sep 2020 21:37:49
User entered 'No (N)'	System	25 Sep 2020 21:37:49

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-25T16:37:39', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '41ed7967-bf13-4066-80eb-5cd3250b1010' User entered 'No (N)'	System	25 Sep 2020 21:37:49
	System	25 Sep 2020 21:37:49

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-25T16:37:43', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '41ed7967-bf13-4066-80eb-5cd3250b1010'	System	25 Sep 2020 21:37:49
User entered 'None (1)'	System	25 Sep 2020 21:37:49



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-25T16:37:47', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '41ed7967-bf13-4066-80eb-5cd3250b1010' User entered '25 Sep 2020 16:37'	System	25 Sep 2020 21:37:49
	System	25 Sep 2020 21:37:49

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 3'	System	24 Sep 2020 15:43:14

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-26T17:03:58', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '59b392a3-ee77-42ae-b207-d2dca14b5288' User entered 'None (1)'	System	26 Sep 2020 22:04:13
	System	26 Sep 2020 22:04:13

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-26T17:04:01', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '59b392a3-ee77-42ae-b207-d2dca14b5288' User entered 'No (N)'	System	26 Sep 2020 22:04:13
	System	26 Sep 2020 22:04:13

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-26T17:04:05', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '59b392a3-ee77-42ae-b207-d2dca14b5288' User entered 'No (N)'	System	26 Sep 2020 22:04:13
	System	26 Sep 2020 22:04:13

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-26T17:04:08', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '59b392a3-ee77-42ae-b207-d2dca14b5288' User entered 'None (1)'	System	26 Sep 2020 22:04:13
	System	26 Sep 2020 22:04:13



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-26T17:04:12', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '59b392a3-ee77-42ae-b207-d2dca14b5288' User entered '26 Sep 2020 17:04'	System	26 Sep 2020 22:04:13
	System	26 Sep 2020 22:04:13

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 4'	System	24 Sep 2020 15:43:14

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-27T18:07:45', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'aefe7eb9-3717-4ebc-bd78-e1be07adca73'	System	27 Sep 2020 23:08:05
User entered 'None (1)'	System	27 Sep 2020 23:08:05

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-27T18:07:47', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'ae7e7eb9-3717-4ebc-bd78-e1be07adca73' User entered 'No (N)'	System	27 Sep 2020 23:08:05
	System	27 Sep 2020 23:08:05

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-27T18:07:50', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'ae7e7eb9-3717-4ebc-bd78-e1be07adca73' User entered 'No (N)'	System	27 Sep 2020 23:08:05
	System	27 Sep 2020 23:08:05

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-27T18:07:54', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'ae7e7eb9-3717-4ebc-bd78-e1be07adca73'	System	27 Sep 2020 23:08:05
User entered 'None (1)'	System	27 Sep 2020 23:08:05



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-27T18:07:59', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'ae7e7eb9-3717-4ebc-bd78-e1be07adca73' User entered '27 Sep 2020 18:07'	System	27 Sep 2020 23:08:05
	System	27 Sep 2020 23:08:05

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 5'	System	24 Sep 2020 15:43:14

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-28T22:15:19', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd684f6c6-e797-436b-8abb-68503349ca10'	System	29 Sep 2020 03:15:37
User entered 'None (1)'	System	29 Sep 2020 03:15:37

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:43:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-28T22:15:22', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd684f6c6-e797-436b-8abb-68503349ca10' User entered 'No (N)'	System	29 Sep 2020 03:15:37
	System	29 Sep 2020 03:15:37

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-28T22:15:27', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd684f6c6-e797-436b-8abb-68503349ca10' User entered 'No (N)'	System	29 Sep 2020 03:15:37
	System	29 Sep 2020 03:15:37

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-28T22:15:30', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd684f6c6-e797-436b-8abb-68503349ca10' User entered 'None (1)'	System	29 Sep 2020 03:15:37
	System	29 Sep 2020 03:15:37



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-28T22:15:33', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'd684f6c6-e797-436b-8abb-68503349ca10' User entered '28 Sep 2020 22:15'	System	29 Sep 2020 03:15:37
	System	29 Sep 2020 03:15:37

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 6'	System	24 Sep 2020 15:43:14

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-29T15:32:56', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '393891e8-730a-42ea-8a66-79f16fe2ac27'	System	29 Sep 2020 20:33:17
User entered 'None (1)'	System	29 Sep 2020 20:33:17

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-29T15:33:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '393891e8-730a-42ea-8a66-79f16fe2ac27'	System	29 Sep 2020 20:33:17
User entered 'No (N)'	System	29 Sep 2020 20:33:17

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:43:22

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-29T15:33:08', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '393891e8-730a-42ea-8a66-79f16fe2ac27'	System	29 Sep 2020 20:33:17
User entered 'No (N)'	System	29 Sep 2020 20:33:17

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-29T15:33:12', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '393891e8-730a-42ea-8a66-79f16fe2ac27'	System	29 Sep 2020 20:33:17
User entered 'None (1)'	System	29 Sep 2020 20:33:17



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-29T15:33:15', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '393891e8-730a-42ea-8a66-79f16fe2ac27' User entered '29 Sep 2020 15:33'	System	29 Sep 2020 20:33:17
	System	29 Sep 2020 20:33:17

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 7'	System	24 Sep 2020 15:43:14

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-30T17:52:11', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'be7c5e9d-ac28-4b1c-9359-dc19063c5045'	System	30 Sep 2020 22:52:29
User entered 'None (1)'	System	30 Sep 2020 22:52:29

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:43:22

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-30T17:52:14', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'be7c5e9d-ac28-4b1c-9359-dc19063c5045' User entered 'No (N)'	System	30 Sep 2020 22:52:29
	System	30 Sep 2020 22:52:29

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-30T17:52:18', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'be7c5e9d-ac28-4b1c-9359-dc19063c5045' User entered 'No (N)'	System	30 Sep 2020 22:52:29
	System	30 Sep 2020 22:52:29

US3782100

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-30T17:52:22', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'be7c5e9d-ac28-4b1c-9359-dc19063c5045'	System	30 Sep 2020 22:52:29
User entered 'None (1)'	System	30 Sep 2020 22:52:29



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-30T17:52:26', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'be7c5e9d-ac28-4b1c-9359-dc19063c5045' User entered '30 Sep 2020 17:52'	System	30 Sep 2020 22:52:29
	System	30 Sep 2020 22:52:29

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 15:43:14

US3782100

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T11:18:10', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '6cae7c99-2cca-4025-92fd-fae55e65297a' User entered 'None (0)'	System	24 Sep 2020 16:18:39
	System	24 Sep 2020 16:18:39

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T11:18:13', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '6cae7c99-2cca-4025-92fd-fae55e65297a' User entered 'None (0)'	System	24 Sep 2020 16:18:39
	System	24 Sep 2020 16:18:39

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T11:18:17', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '6cae7c99-2cca-4025-92fd-fae55e65297a' User entered 'None (0)'	System	24 Sep 2020 16:18:39
	System	24 Sep 2020 16:18:39

US3782100

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T11:18:21', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '6cae7c99-2cca-4025-92fd-fae55e65297a' User entered 'None (0)'	System	24 Sep 2020 16:18:39
	System	24 Sep 2020 16:18:39



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T11:18:24', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '6cae7c99-2cca-4025-92fd-fae55e65297a' User entered 'None (0)'	System	24 Sep 2020 16:18:39
	System	24 Sep 2020 16:18:39

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T11:18:26', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '6cae7c99-2cca-4025-92fd-fae55e65297a' User entered 'None (0)'	System	24 Sep 2020 16:18:39
	System	24 Sep 2020 16:18:39

US3782100

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T11:18:31', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '6cae7c99-2cca-4025-92fd-fae55e65297a' User entered 'No (N)'	System	24 Sep 2020 16:18:39
	System	24 Sep 2020 16:18:39

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T11:18:34', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '6cae7c99-2cca-4025-92fd-fae55e65297a' User entered '24 Sep 2020 11:18'	System	24 Sep 2020 16:18:39
	System	24 Sep 2020 16:18:39

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '24 Sep 2020 10:58'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '24 Sep 2020 13:28'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T20:06:30', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'bc7c016c-e180-4e22-b848-6cac2c7909c2' User entered 'None (0)'	System	25 Sep 2020 01:06:52
	System	25 Sep 2020 01:06:52



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T20:06:32', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'bc7c016c-e180-4e22-b848-6cac2c7909c2' User entered 'None (0)'	System	25 Sep 2020 01:06:52
	System	25 Sep 2020 01:06:52

US3782100

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T20:06:36', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'bc7c016c-e180-4e22-b848-6cac2c7909c2' User entered 'None (0)'	System	25 Sep 2020 01:06:52
	System	25 Sep 2020 01:06:52

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T20:06:39', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'bc7c016c-e180-4e22-b848-6cac2c7909c2' User entered 'None (0)'	System	25 Sep 2020 01:06:52
	System	25 Sep 2020 01:06:52

US3782100

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T20:06:41', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'bc7c016c-e180-4e22-b848-6cac2c7909c2' User entered 'None (0)'	System	25 Sep 2020 01:06:52
	System	25 Sep 2020 01:06:52

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T20:06:43', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'bc7c016c-e180-4e22-b848-6cac2c7909c2' User entered 'None (0)'	System	25 Sep 2020 01:06:52
	System	25 Sep 2020 01:06:52

US3782100

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T20:06:46', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'bc7c016c-e180-4e22-b848-6cac2c7909c2'	System	25 Sep 2020 01:06:52
User entered 'No (N)'	System	25 Sep 2020 01:06:52

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-24T20:06:49', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'bc7c016c-e180-4e22-b848-6cac2c7909c2' User entered '24 Sep 2020 20:06'	System	25 Sep 2020 01:06:52
	System	25 Sep 2020 01:06:52

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '24 Sep 2020 14:23'	System	24 Sep 2020 15:43:14



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '25 Sep 2020 11:59'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 2'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-25T16:37:53', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7e28eb8a-93d6-4984-be57-1728ecac2e76' User entered 'None (0)'	System	25 Sep 2020 21:38:19
	System	25 Sep 2020 21:38:19

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-25T16:37:55', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7e28eb8a-93d6-4984-be57-1728ecac2e76' User entered 'None (0)'	System	25 Sep 2020 21:38:19
	System	25 Sep 2020 21:38:19

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-25T16:37:59', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7e28eb8a-93d6-4984-be57-1728ecac2e76' User entered 'None (0)'	System	25 Sep 2020 21:38:19
	System	25 Sep 2020 21:38:19

US3782100

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:43:22

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-25T16:38:02', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7e28eb8a-93d6-4984-be57-1728ecac2e76' User entered 'None (0)'	System	25 Sep 2020 21:38:19
	System	25 Sep 2020 21:38:19

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-25T16:38:06', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7e28eb8a-93d6-4984-be57-1728ecac2e76' User entered 'None (0)'	System	25 Sep 2020 21:38:19
	System	25 Sep 2020 21:38:19

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-25T16:38:08', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7e28eb8a-93d6-4984-be57-1728ecac2e76' User entered 'None (0)'	System	25 Sep 2020 21:38:19
	System	25 Sep 2020 21:38:19



US3782100

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-25T16:38:13', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7e28eb8a-93d6-4984-be57-1728ecac2e76' User entered 'No (N)'	System	25 Sep 2020 21:38:19
	System	25 Sep 2020 21:38:19

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-25T16:38:17', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7e28eb8a-93d6-4984-be57-1728ecac2e76' User entered '25 Sep 2020 16:38'	System	25 Sep 2020 21:38:19
	System	25 Sep 2020 21:38:19

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '25 Sep 2020 12:00'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '26 Sep 2020 11:59'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 3'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-26T17:04:18', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '0b4b0fa2-50ab-4b50-81f1-3c7185aec607' User entered 'None (0)'	System	26 Sep 2020 22:04:42
	System	26 Sep 2020 22:04:42

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-26T17:04:21', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '0b4b0fa2-50ab-4b50-81f1-3c7185aec607' User entered 'None (0)'	System	26 Sep 2020 22:04:42
	System	26 Sep 2020 22:04:42

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-26T17:04:24', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '0b4b0fa2-50ab-4b50-81f1-3c7185aec607' User entered 'None (0)'	System	26 Sep 2020 22:04:42
	System	26 Sep 2020 22:04:42



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-26T17:04:27', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '0b4b0fa2-50ab-4b50-81f1-3c7185aec607' User entered 'None (0)'	System	26 Sep 2020 22:04:42
	System	26 Sep 2020 22:04:42

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-26T17:04:30', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '0b4b0fa2-50ab-4b50-81f1-3c7185aec607' User entered 'None (0)'	System	26 Sep 2020 22:04:42
	System	26 Sep 2020 22:04:42

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-26T17:04:32', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '0b4b0fa2-50ab-4b50-81f1-3c7185aec607' User entered 'None (0)'	System	26 Sep 2020 22:04:42
	System	26 Sep 2020 22:04:42

US3782100

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-26T17:04:36', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '0b4b0fa2-50ab-4b50-81f1-3c7185aec607' User entered 'No (N)'	System	26 Sep 2020 22:04:42
	System	26 Sep 2020 22:04:42

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-26T17:04:40', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '0b4b0fa2-50ab-4b50-81f1-3c7185aec607' User entered '26 Sep 2020 17:04'	System	26 Sep 2020 22:04:42
	System	26 Sep 2020 22:04:42

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '26 Sep 2020 12:00'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '27 Sep 2020 11:59'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 4'	System	24 Sep 2020 15:43:14



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-27T18:08:06', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'e7cd7786-c303-4d5b-a7c5-3f01590b1b31' User entered 'None (0)'	System	27 Sep 2020 23:08:25
	System	27 Sep 2020 23:08:25

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-27T18:08:08', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'e7cd7786-c303-4d5b-a7c5-3f01590b1b31' User entered 'None (0)'	System	27 Sep 2020 23:08:25
	System	27 Sep 2020 23:08:25

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-27T18:08:10', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'e7cd7786-c303-4d5b-a7c5-3f01590b1b31' User entered 'None (0)'	System	27 Sep 2020 23:08:25
	System	27 Sep 2020 23:08:25

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-27T18:08:12', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'e7cd7786-c303-4d5b-a7c5-3f01590b1b31' User entered 'None (0)'	System	27 Sep 2020 23:08:25
	System	27 Sep 2020 23:08:25

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-27T18:08:14', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'e7cd7786-c303-4d5b-a7c5-3f01590b1b31' User entered 'None (0)'	System	27 Sep 2020 23:08:25
	System	27 Sep 2020 23:08:25

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-27T18:08:16', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'e7cd7786-c303-4d5b-a7c5-3f01590b1b31' User entered 'None (0)'	System	27 Sep 2020 23:08:25
	System	27 Sep 2020 23:08:25

US3782100

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:43:22

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-27T18:08:19', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'e7cd7786-c303-4d5b-a7c5-3f01590b1b31'	System	27 Sep 2020 23:08:25
User entered 'No (N)'	System	27 Sep 2020 23:08:25

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-27T18:08:22', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'e7cd7786-c303-4d5b-a7c5-3f01590b1b31' User entered '27 Sep 2020 18:08'	System	27 Sep 2020 23:08:25
	System	27 Sep 2020 23:08:25



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '27 Sep 2020 12:00'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '28 Sep 2020 11:59'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 5'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-28T22:15:41', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7339ad63-6b60-4ac4-b9eb-482818535b09' User entered 'None (0)'	System	29 Sep 2020 03:16:03
	System	29 Sep 2020 03:16:03

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-28T22:15:44', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7339ad63-6b60-4ac4-b9eb-482818535b09' User entered 'None (0)'	System	29 Sep 2020 03:16:03
	System	29 Sep 2020 03:16:03

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-28T22:15:46', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7339ad63-6b60-4ac4-b9eb-482818535b09' User entered 'None (0)'	System	29 Sep 2020 03:16:03
	System	29 Sep 2020 03:16:03

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-28T22:15:49', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7339ad63-6b60-4ac4-b9eb-482818535b09' User entered 'None (0)'	System	29 Sep 2020 03:16:03
	System	29 Sep 2020 03:16:03

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-28T22:15:51', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7339ad63-6b60-4ac4-b9eb-482818535b09' User entered 'None (0)'	System	29 Sep 2020 03:16:03
	System	29 Sep 2020 03:16:03



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-28T22:15:53', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7339ad63-6b60-4ac4-b9eb-482818535b09' User entered 'None (0)'	System	29 Sep 2020 03:16:03
	System	29 Sep 2020 03:16:03

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-28T22:15:57', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7339ad63-6b60-4ac4-b9eb-482818535b09' User entered 'No (N)'	System	29 Sep 2020 03:16:03
	System	29 Sep 2020 03:16:03

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-28T22:16:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7339ad63-6b60-4ac4-b9eb-482818535b09' User entered '28 Sep 2020 22:16'	System	29 Sep 2020 03:16:03
	System	29 Sep 2020 03:16:03

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '28 Sep 2020 12:00'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '29 Sep 2020 11:59'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 6'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-29T15:33:20', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '5da12328-7fb8-4e2f-8be0-d040478ad4c3' User entered 'None (0)'	System	29 Sep 2020 20:33:44
	System	29 Sep 2020 20:33:44

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-29T15:33:22', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '5da12328-7fb8-4e2f-8be0-d040478ad4c3' User entered 'None (0)'	System	29 Sep 2020 20:33:44
	System	29 Sep 2020 20:33:44



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-29T15:33:25', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '5da12328-7fb8-4e2f-8be0-d040478ad4c3' User entered 'None (0)'	System	29 Sep 2020 20:33:44
	System	29 Sep 2020 20:33:44

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-29T15:33:28', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '5da12328-7fb8-4e2f-8be0-d040478ad4c3' User entered 'None (0)'	System	29 Sep 2020 20:33:44
	System	29 Sep 2020 20:33:44

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-29T15:33:30', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '5da12328-7fb8-4e2f-8be0-d040478ad4c3' User entered 'None (0)'	System	29 Sep 2020 20:33:44
	System	29 Sep 2020 20:33:44

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-29T15:33:33', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '5da12328-7fb8-4e2f-8be0-d040478ad4c3' User entered 'None (0)'	System	29 Sep 2020 20:33:44
	System	29 Sep 2020 20:33:44

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-29T15:33:39', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '5da12328-7fb8-4e2f-8be0-d040478ad4c3' User entered 'No (N)'	System	29 Sep 2020 20:33:44
	System	29 Sep 2020 20:33:44

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-29T15:33:42', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '5da12328-7fb8-4e2f-8be0-d040478ad4c3' User entered '29 Sep 2020 15:33'	System	29 Sep 2020 20:33:44
	System	29 Sep 2020 20:33:44

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '29 Sep 2020 12:00'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '30 Sep 2020 11:59'	System	24 Sep 2020 15:43:14



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	24 Sep 2020 15:43:14
User entered 'Day 7'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-30T17:52:32', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '374faf95-1dc1-4147-a58d-fb1f82d4dbbf' User entered 'None (0)'	System	30 Sep 2020 22:52:51
	System	30 Sep 2020 22:52:51

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-30T17:52:34', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '374faf95-1dc1-4147-a58d-fb1f82d4dbbf' User entered 'None (0)'	System	30 Sep 2020 22:52:51
	System	30 Sep 2020 22:52:51

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-30T17:52:36', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '374faf95-1dc1-4147-a58d-fb1f82d4dbbf' User entered 'None (0)'	System	30 Sep 2020 22:52:51
	System	30 Sep 2020 22:52:51

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-30T17:52:38', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '374faf95-1dc1-4147-a58d-fb1f82d4dbbf' User entered 'None (0)'	System	30 Sep 2020 22:52:51
	System	30 Sep 2020 22:52:51

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-30T17:52:40', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '374faf95-1dc1-4147-a58d-fb1f82d4dbbf' User entered 'None (0)'	System	30 Sep 2020 22:52:51
	System	30 Sep 2020 22:52:51

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-30T17:52:43', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '374faf95-1dc1-4147-a58d-fb1f82d4dbbf' User entered 'None (0)'	System	30 Sep 2020 22:52:51
	System	30 Sep 2020 22:52:51

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

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 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-30T17:52:47', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '374faf95-1dc1-4147-a58d-fb1f82d4dbbf' User entered 'No (N)'	System	30 Sep 2020 22:52:51
	System	30 Sep 2020 22:52:51



**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-09-30T17:52:49', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '374faf95-1dc1-4147-a58d-fb1f82d4dbbf' User entered '30 Sep 2020 17:52'	System	30 Sep 2020 22:52:51
	System	30 Sep 2020 22:52:51

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '30 Sep 2020 12:00'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 10 Jun 2021 09:43:22**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
User entered '01 Oct 2020 11:59'	System	24 Sep 2020 15:43:14

**US3782100**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Amy Kerrigan (b) (4)	01 Oct 2020 13:46:40

**US3782100**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '1 Oct 2020'	(b) (4) Amy Kerrigan (b) (4) (b) (4)	01 Oct 2020 13:46:40

**US3782100**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Amy Kerrigan (b) (4)	01 Oct 2020 13:46:40

**US3782100**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	Amy Kerrigan (b) (4)	01 Oct 2020 13:46:40

**US3782100**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Amy Kerrigan (b) (4)	01 Oct 2020 13:47:20



**US3782100**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'I'	System	01 Oct 2020 13:47:20

**US3782100**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	08 Oct 2020 13:51:17

**US3782100**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '8 Oct 2020'	Carlton Griffin (b) (4)	08 Oct 2020 13:51:17

**US3782100**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Contact Made (CONTACT MADE)'	Carlton Griffin (b) (4)	08 Oct 2020 13:51:17

**US3782100**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) Carlton Griffin (b) (4)	08 Oct 2020 13:51:17

**US3782100**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	08 Oct 2020 13:51:21

**US3782100**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'I'	System	08 Oct 2020 13:51:21

**US3782100**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	15 Oct 2020 13:43:25



**US3782100**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '15 Oct 2020'	(b) (4) Carlton Griffin (b) (4)	15 Oct 2020 13:43:25

**US3782100**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	15 Oct 2020 13:43:25

**US3782100**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	Carlton Griffin (b) (4)	15 Oct 2020 13:43:25

**US3782100**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	15 Oct 2020 13:43:30

**US3782100**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'I'	System	15 Oct 2020 13:43:30

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 12:51:22

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '22 Oct 2020'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 12:51:22

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[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 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Clinic (Clinic)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Oct 2020 12:51:22



**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'VISIT3'	System	22 Oct 2020 12:51:22

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 12:51:54

US3782100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '22 Oct 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Oct 2020 12:51:54

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '07:35'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Oct 2020 12:51:54

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered '22 Oct 2020 07:35'	System	22 Oct 2020 12:51:54

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '97.6' F	Carlton Griffin (b) (4)	22 Oct 2020 12:51:54

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Oral (Oral)'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 12:51:54

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 12:51:54



**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '64'	Carlton Griffin (b) (4)	22 Oct 2020 12:51:54

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'bpm'	System	22 Oct 2020 12:51:54

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '16'	Carlton Griffin (b) (4)	22 Oct 2020 12:51:54

US3782100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:22

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'breaths/min'	System	22 Oct 2020 12:51:54

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '147'	Carlton Griffin (b) (4)	22 Oct 2020 12:51:54

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'mmHg'	System	22 Oct 2020 12:51:54

US3782100

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '73'	Carlton Griffin (b) (4)	22 Oct 2020 12:51:54

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'mmHg'	System	22 Oct 2020 12:51:54



**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:43:22**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 12:52:01

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:43:22**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '22 Oct 2020'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 12:52:01

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:43:22**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 12:52:12

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:43:22**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '22 Oct 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Oct 2020 12:52:12

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:43:22**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '07:40'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Oct 2020 12:52:12

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:43:22**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered '22 Oct 2020 07:40'	System	22 Oct 2020 12:52:12



**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 12:52:17

**US3782100**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'I'	System	22 Oct 2020 12:52:17

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 64'	System	27 Aug 2020 18:28:33

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-10-29T12:28:01', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'a2b507c1-96ee-4054-bad6-9efef147ecf7'	System	29 Oct 2020 17:28:42
User entered 'No (N)'	System	29 Oct 2020 17:28:42

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-10-29T12:28:10', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'a2b507c1-96ee-4054-bad6-9efef147ecf7'	System	29 Oct 2020 17:28:42
User entered 'No (N)'	System	29 Oct 2020 17:28:42

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-10-29T12:28:34', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'a2b507c1-96ee-4054-bad6-9efef147ecf7' User entered '29 Oct 2020 12:28:34'	System	29 Oct 2020 17:28:42
	System	29 Oct 2020 17:28:42

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered '27 Oct 2020 00:01'	System	27 Aug 2020 18:28:33

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered '31 Oct 2020 23:59'	System	27 Aug 2020 18:28:33



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 71'	System	27 Aug 2020 18:28:33

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-11-03T15:34:34', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '94d3c818-3d51-47f0-964c-a688a32803b6'	System	03 Nov 2020 21:34:51
User entered 'No (N)'	System	03 Nov 2020 21:34:51

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-11-03T15:34:39', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '94d3c818-3d51-47f0-964c-a688a32803b6' User entered 'No (N)'	System	03 Nov 2020 21:34:51
	System	03 Nov 2020 21:34:51

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-11-03T15:34:46', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '94d3c818-3d51-47f0-964c-a688a32803b6' User entered '03 Nov 2020 15:34:46'	System	03 Nov 2020 21:34:51
	System	03 Nov 2020 21:34:51

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered '03 Nov 2020 00:01'	System	27 Aug 2020 18:28:33

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered '07 Nov 2020 23:59'	System	27 Aug 2020 18:28:33

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered 'Day 78'	System	27 Aug 2020 18:28:33

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-11-11T09:54:44', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '6b5e5c49-32f3-478e-ac6a-221ea65afa22'	System	11 Nov 2020 15:54:56
User entered 'No (N)'	System	11 Nov 2020 15:54:56



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-11-11T09:54:48', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '6b5e5c49-32f3-478e-ac6a-221ea65afa22'	System	11 Nov 2020 15:54:56
User entered 'No (N)'	System	11 Nov 2020 15:54:56

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-11-11T09:54:54', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '6b5e5c49-32f3-478e-ac6a-221ea65afa22'	System	11 Nov 2020 15:54:56
User entered '11 Nov 2020 09:54:54'	System	11 Nov 2020 15:54:56

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered '10 Nov 2020 00:01'	System	27 Aug 2020 18:28:33

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 08:56:26
Data entry locked.	System	27 Aug 2020 18:28:33
User entered '14 Nov 2020 23:59'	System	27 Aug 2020 18:28:33

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-11-23T11:49:08', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '2b4a08ff-2b41-4020-a639-1f1ccebc43fc' User entered 'No (N)'	System	23 Nov 2020 17:49:19

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-11-23T11:49:12', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '2b4a08ff-2b41-4020-a639-1f1ccebc43fc' User entered 'No (N)'	System	23 Nov 2020 17:49:19

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-11-23T11:49:16', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '2b4a08ff-2b41-4020-a639-1f1cceb43fc' User entered '23 Nov 2020 11:49:16'	System	23 Nov 2020 17:49:19



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-11-28T06:48:25', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'c2b1a668-f4de-4bb2-9bbe-f781a2a9de15'	System	28 Nov 2020 12:48:53
User entered 'No (N)'	System	28 Nov 2020 12:48:53

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-11-28T06:48:38', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'c2b1a668-f4de-4bb2-9bbe-f781a2a9de15'	System	28 Nov 2020 12:48:53
User entered 'No (N)'	System	28 Nov 2020 12:48:53

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-11-28T06:48:51', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'c2b1a668-f4de-4bb2-9bbe-f781a2a9de15' User entered '28 Nov 2020 06:48:51'	System	28 Nov 2020 12:48:53
	System	28 Nov 2020 12:48:53

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 19:14:35



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-12-05T06:59:30', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '0c2e0b6f-9ab6-409f-ba3f-652b9e6d7171' User entered 'Yes (Y)'	System	05 Dec 2020 13:00:33
	System	05 Dec 2020 13:00:33

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-12-05T06:59:39', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '0c2e0b6f-9ab6-409f-ba3f-652b9e6d7171'	System	05 Dec 2020 13:00:33
User entered 'No (N)'	System	05 Dec 2020 13:00:33

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-12-05T06:59:47', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '0c2e0b6f-9ab6-409f-ba3f-652b9e6d7171' User entered 'No (N)'	System	05 Dec 2020 13:00:33
	System	05 Dec 2020 13:00:33

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-12-05T06:59:58', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '0c2e0b6f-9ab6-409f-ba3f-652b9e6d7171' User entered 'Yes (Y)'	System	05 Dec 2020 13:00:33
	System	05 Dec 2020 13:00:33

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-12-05T07:00:13', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '0c2e0b6f-9ab6-409f-ba3f-652b9e6d7171'	System	05 Dec 2020 13:00:33
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Dec 2020 13:00:33

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-12-05T07:00:24', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '0c2e0b6f-9ab6-409f-ba3f-652b9e6d7171' User entered '05 Dec 2020 07:00:24'	System	05 Dec 2020 13:00:33
	System	05 Dec 2020 13:00:33

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 19:14:35



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-12-12T07:53:38', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'dc8e0ba7-f8bb-4078-82de-675255ed28f6'	System	12 Dec 2020 13:53:53
User entered 'No (N)'	System	12 Dec 2020 13:53:53

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-12-12T07:53:43', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'dc8e0ba7-f8bb-4078-82de-675255ed28f6'	System	12 Dec 2020 13:53:53
User entered 'No (N)'	System	12 Dec 2020 13:53:53

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-12-12T07:53:50', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'dc8e0ba7-f8bb-4078-82de-675255ed28f6' User entered '12 Dec 2020 07:53:50'	System	12 Dec 2020 13:53:53
	System	12 Dec 2020 13:53:53

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 19:14:35



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-12-20T07:51:54', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '370d5ef4-e5f8-401b-b14e-c104ff9a0de9' User entered 'No (N)'	System	20 Dec 2020 13:52:23
	System	20 Dec 2020 13:52:23

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-12-20T07:52:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '370d5ef4-e5f8-401b-b14e-c104ff9a0de9' User entered 'No (N)'	System	20 Dec 2020 13:52:23
	System	20 Dec 2020 13:52:23

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-12-20T07:52:19', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '370d5ef4-e5f8-401b-b14e-c104ff9a0de9' User entered '20 Dec 2020 07:52:19'	System	20 Dec 2020 13:52:23
	System	20 Dec 2020 13:52:23

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-12-28T11:12:59', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '35bc8aac-8fc3-4ec6-a50c-a99f78e90520' User entered 'No (N)'	System	28 Dec 2020 17:13:13
	System	28 Dec 2020 17:13:13

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-12-28T11:13:03', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '35bc8aac-8fc3-4ec6-a50c-a99f78e90520' User entered 'No (N)'	System	28 Dec 2020 17:13:13
	System	28 Dec 2020 17:13:13



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2020-12-28T11:13:07', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '35bc8aac-8fc3-4ec6-a50c-a99f78e90520' User entered '28 Dec 2020 11:13:07'	System	28 Dec 2020 17:13:13
	System	28 Dec 2020 17:13:13

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-01-04T10:12:27', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '23e56b86-86d1-432a-94e6-2aa871b0378a' User entered 'No (N)'	System	04 Jan 2021 16:12:48
	System	04 Jan 2021 16:12:48

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-01-04T10:12:35', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '23e56b86-86d1-432a-94e6-2aa871b0378a' User entered 'No (N)'	System	04 Jan 2021 16:12:48
	System	04 Jan 2021 16:12:48

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-01-04T10:12:46', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '23e56b86-86d1-432a-94e6-2aa871b0378a' User entered '04 Jan 2021 10:12:46'	System	04 Jan 2021 16:12:48
	System	04 Jan 2021 16:12:48

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 19:14:35



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-01-09T06:52:16', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'a0107217-7615-4934-a7ca-2eda0eba6378' User entered 'No (N)'	System	09 Jan 2021 12:52:37
	System	09 Jan 2021 12:52:37

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-01-09T06:52:23', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'a0107217-7615-4934-a7ca-2eda0eba6378' User entered 'No (N)'	System	09 Jan 2021 12:52:37

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-01-09T06:52:35', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'a0107217-7615-4934-a7ca-2eda0eba6378' User entered '09 Jan 2021 06:52:35'	System	09 Jan 2021 12:52:37

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 19:14:35



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-01-18T10:00:19', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'a03eb5ed-7e6c-455d-af55-1abf47ebf639'	System	18 Jan 2021 16:00:31
User entered 'No (N)'	System	18 Jan 2021 16:00:31

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-01-18T10:00:23', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'a03eb5ed-7e6c-455d-af55-1abf47ebf639'	System	18 Jan 2021 16:00:31
User entered 'No (N)'	System	18 Jan 2021 16:00:31

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-01-18T10:00:27', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'a03eb5ed-7e6c-455d-af55-1abf47ebf639' User entered '18 Jan 2021 10:00:27'	System	18 Jan 2021 16:00:31
	System	18 Jan 2021 16:00:31

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-01-25T10:05:27', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '94cedce5-486a-472e-9a38-370aa47bb83d' User entered 'No (N)'	System	25 Jan 2021 16:05:38
	System	25 Jan 2021 16:05:38

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-01-25T10:05:30', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '94cedce5-486a-472e-9a38-370aa47bb83d' User entered 'No (N)'	System	25 Jan 2021 16:05:38
	System	25 Jan 2021 16:05:38



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-01-25T10:05:35', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '94cedce5-486a-472e-9a38-370aa47bb83d' User entered '25 Jan 2021 10:05:35'	System	25 Jan 2021 16:05:38
	System	25 Jan 2021 16:05:38

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-02-01T12:57:33', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'afbff1db-fd18-4db0-992d-3efd7b39082c' User entered 'No (N)'	System	01 Feb 2021 18:57:42

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-02-01T12:57:35', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'afbff1db-fd18-4db0-992d-3efd7b39082c' User entered 'No (N)'	System	01 Feb 2021 18:57:42

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-02-01T12:57:40', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'afbff1db-fd18-4db0-992d-3efd7b39082c' User entered '01 Feb 2021 12:57:40'	System	01 Feb 2021 18:57:42
	System	01 Feb 2021 18:57:42

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 19:14:35



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-02-08T10:18:53', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7b0c7345-c2a3-477a-8ddb-d099f2ef24c8'	System	08 Feb 2021 16:19:03
User entered 'No (N)'	System	08 Feb 2021 16:19:03

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-02-08T10:18:57', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7b0c7345-c2a3-477a-8ddb-d099f2ef24c8'	System	08 Feb 2021 16:19:03
User entered 'No (N)'	System	08 Feb 2021 16:19:03

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-02-08T10:19:01', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '7b0c7345-c2a3-477a-8ddb-d099f2ef24c8' User entered '08 Feb 2021 10:19:01'	System	08 Feb 2021 16:19:03
	System	08 Feb 2021 16:19:03

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 19:14:35



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-02-13T01:25:05', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '93aaec69-619f-40cd-9148-451f7e55b750' User entered 'No (N)'	System	13 Feb 2021 07:25:16
	System	13 Feb 2021 07:25:16

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-02-13T01:25:09', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '93aaec69-619f-40cd-9148-451f7e55b750'	System	13 Feb 2021 07:25:16
User entered 'No (N)'	System	13 Feb 2021 07:25:16

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-02-13T01:25:13', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '93aaec69-619f-40cd-9148-451f7e55b750' User entered '13 Feb 2021 01:25:13'	System	13 Feb 2021 07:25:16
	System	13 Feb 2021 07:25:16

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-02-20T19:34:23', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'fe02094b-180d-48e0-9b03-aef12ddfee59'	System	21 Feb 2021 01:34:37
User entered 'No (N)'	System	21 Feb 2021 01:34:37

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-02-20T19:34:25', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'fe02094b-180d-48e0-9b03-aef12ddfee59' User entered 'No (N)'	System	21 Feb 2021 01:34:37
	System	21 Feb 2021 01:34:37



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-02-20T19:34:34', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'fe02094b-180d-48e0-9b03-aef12ddfee59' User entered '20 Feb 2021 19:34:34'	System	21 Feb 2021 01:34:37
	System	21 Feb 2021 01:34:37

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-02-28T11:39:05-06:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '4c375555-ba6d-4da2-bfd0-67cca7dd789d' User entered 'No (N)'	System	28 Feb 2021 17:39:16
	System	28 Feb 2021 17:39:16

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-02-28T11:39:09-06:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '4c375555-ba6d-4da2-bfd0-67cca7dd789d' User entered 'No (N)'	System	28 Feb 2021 17:39:16
	System	28 Feb 2021 17:39:16

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-02-28T11:39:13-06:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '4c375555-ba6d-4da2-bfd0-67cca7dd789d' User entered '28 Feb 2021 17:39:13'	System	28 Feb 2021 17:39:16
	System	28 Feb 2021 17:39:16

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 19:14:35



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-03-07T10:34:09-06:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '56ac973b-09f0-434a-b929-10cf42ea48aa'	System	07 Mar 2021 16:34:22
User entered 'No (N)'	System	07 Mar 2021 16:34:22

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-03-07T10:34:14-06:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '56ac973b-09f0-434a-b929-10cf42ea48aa'	System	07 Mar 2021 16:34:22
User entered 'No (N)'	System	07 Mar 2021 16:34:22

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-03-07T10:34:19-06:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '56ac973b-09f0-434a-b929-10cf42ea48aa'	System	07 Mar 2021 16:34:22
User entered '07 Mar 2021 10:34:19'	System	07 Mar 2021 16:34:22

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 19:14:35



**US3782100**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-03-15T09:34:33-05:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '2461fec4-0d62-4e9a-bd5d-06a6c54d922f' User entered 'No (N)'	System	15 Mar 2021 14:34:42
	System	15 Mar 2021 14:34:42

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-03-15T09:34:35-05:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '2461fec4-0d62-4e9a-bd5d-06a6c54d922f' User entered 'No (N)'	System	15 Mar 2021 14:34:42

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-03-15T09:34:40-05:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '2461fec4-0d62-4e9a-bd5d-06a6c54d922f' User entered '15 Mar 2021 09:34:40'	System	15 Mar 2021 14:34:42
	System	15 Mar 2021 14:34:42

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-03-22T09:09:43-05:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '3372e665-8808-4946-8bc3-d1d937dc0c6e'	System	22 Mar 2021 14:09:54
User entered 'No (N)'	System	22 Mar 2021 14:09:54

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-03-22T09:09:47-05:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '3372e665-8808-4946-8bc3-d1d937dc0c6e'	System	22 Mar 2021 14:09:54
User entered 'No (N)'	System	22 Mar 2021 14:09:54



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-03-22T09:09:52-05:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '3372e665-8808-4946-8bc3-d1d937dc0c6e' User entered '22 Mar 2021 09:09:52'	System	22 Mar 2021 14:09:54

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-03-29T06:31:51-05:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'ada3e3f5-56ce-479b-900c-cd895c1223af'	System	29 Mar 2021 11:32:17
User entered 'No (N)'	System	29 Mar 2021 11:32:17

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-03-29T06:31:57-05:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'ada3e3f5-56ce-479b-900c-cd895c1223af'	System	29 Mar 2021 11:32:17
User entered 'No (N)'	System	29 Mar 2021 11:32:17

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-03-29T06:32:11-05:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'ada3e3f5-56ce-479b-900c-cd895c1223af' User entered '29 Mar 2021 06:32:11'	System	29 Mar 2021 11:32:17
	System	29 Mar 2021 11:32:17

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-04-05T09:23:19-05:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'ef2634d9-3d39-4bed-9b46-e7453cc2a93a'	System	05 Apr 2021 14:23:35
User entered 'No (N)'	System	05 Apr 2021 14:23:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-04-05T09:23:24-05:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'ef2634d9-3d39-4bed-9b46-e7453cc2a93a' User entered 'No (N)'	System	05 Apr 2021 14:23:35
	System	05 Apr 2021 14:23:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-04-05T09:23:28-05:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'ef2634d9-3d39-4bed-9b46-e7453cc2a93a'	System	05 Apr 2021 14:23:35
User entered '05 Apr 2021 09:23:28'	System	05 Apr 2021 14:23:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-04-10T08:37:39-05:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'ad3cddcc-f7d1-4279-aec8-708e2782fce8'	System	10 Apr 2021 13:37:52
User entered 'No (N)'	System	10 Apr 2021 13:37:52

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-04-10T08:37:45-05:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'ad3cddcc-f7d1-4279-aec8-708e2782fce8'	System	10 Apr 2021 13:37:52
User entered 'No (N)'	System	10 Apr 2021 13:37:52

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-04-10T08:37:49-05:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'ad3cddcc-f7d1-4279-aec8-708e2782fce8'	System	10 Apr 2021 13:37:52
User entered '10 Apr 2021 08:37:49'	System	10 Apr 2021 13:37:52

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-04-19T09:29:48-05:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '0e97f614-b657-4845-99bb-caeeb29bab7e'	System	19 Apr 2021 14:30:02
User entered 'No (N)'	System	19 Apr 2021 14:30:02

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-04-19T09:29:51-05:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '0e97f614-b657-4845-99bb-caeeb29bab7e'	System	19 Apr 2021 14:30:02
User entered 'No (N)'	System	19 Apr 2021 14:30:02



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-04-19T09:29:58-05:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '0e97f614-b657-4845-99bb-caeeb29bab7e'	System	19 Apr 2021 14:30:02
User entered '19 Apr 2021 09:29:58'	System	19 Apr 2021 14:30:02

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-04-24T02:27:48-05:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'a7dcdf0a-9cbb-4c00-92f4-3407023d897c' User entered 'No (N)'	System	24 Apr 2021 07:28:07
	System	24 Apr 2021 07:28:07

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Have you been exposed to someone with 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 (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-04-24T02:27:58-05:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'a7dcdf0a-9cbb-4c00-92f4-3407023d897c'	System	24 Apr 2021 07:28:07
User entered 'No (N)'	System	24 Apr 2021 07:28:07

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-04-24T02:28:05-05:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: 'a7dcdf0a-9cbb-4c00-92f4-3407023d897c'	System	24 Apr 2021 07:28:07
User entered '24 Apr 2021 02:28:05'	System	24 Apr 2021 07:28:07

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 19:14:35



**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '29 Oct 2022 00:01'	System	19 Nov 2020 19:14:35

**US3782100**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:43:22**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 19:14:35
Amendment Manager: User entered '02 Nov 2022 23:59'	System	19 Nov 2020 19:14:35

US3782100

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:43:22

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)	29 Apr 2021 19:59:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-02-28T11:38:52-06:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '8af4eb04-22da-4523-be63-79cce76a696f' User entered 'No (N)'	System	28 Feb 2021 17:38:59
	System	28 Feb 2021 17:38:59

**US3782100**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 19:59:34
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (CD4CF601-AEC8-4104-AF98-4D9FEF13D85F)', Time: '2021-02-28T11:38:57-06:00', User OID: 'PatientReportedOutcome (US3782100)', ODM File OID: '8af4eb04-22da-4523-be63-79cce76a696f' User entered '28 Feb 2021 17:38:57'	System	28 Feb 2021 17:38:59
	System	28 Feb 2021 17:38:59



**US3782100**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:54:40

**US3782100**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '19 Nov 2020'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:54:40

**US3782100**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:54:40

**US3782100**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:54:40

**US3782100**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Nov 2020 15:54:49

**US3782100**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:18:59
User entered 'I'	System	19 Nov 2020 15:54:49

**US3782100**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:05:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	22 Dec 2020 20:39:37

**US3782100**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:05:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '22 Dec 2020'	(b) (4) Carlton Griffin (b) (4)	22 Dec 2020 20:39:37
	(b) (4)	



**US3782100**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:05:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	22 Dec 2020 20:39:37

**US3782100**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:05:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered empty.	(b) (4) Carlton Griffin (b) (4)	22 Dec 2020 20:39:37

**US3782100**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:05:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	22 Dec 2020 20:39:43

**US3782100**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:05:32
User entered 'I'	System	22 Dec 2020 20:39:43

**US3782100**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:05:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	22 Jan 2021 15:04:45

**US3782100**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:05:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '22 Jan 2021'	(b) (4) Carlton Griffin (b) (4)	22 Jan 2021 15:04:45
	(b) (4)	

**US3782100**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:05:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	22 Jan 2021 15:04:45

**US3782100**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:05:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered empty.	(b) (4) Carlton Griffin (b) (4)	22 Jan 2021 15:04:45



**US3782100**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:05:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	22 Jan 2021 15:04:36

**US3782100**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:05:32
User entered 'I'	System	22 Jan 2021 15:04:36

**US3782100**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:53:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	21 Feb 2021 20:33:01

**US3782100**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:53:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '21 Feb 2021'	Carlton Griffin (b) (4)	21 Feb 2021 20:33:01

**US3782100**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:53:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'Contact Made (CONTACT MADE)'	Carlton Griffin (b) (4)	21 Feb 2021 20:33:01

**US3782100**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:53:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered empty.	Carlton Griffin (b) (4)	21 Feb 2021 20:33:01

**US3782100**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:53:21
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	21 Feb 2021 20:33:09

**US3782100**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:53:21
User entered 'I'	System	21 Feb 2021 20:33:09



**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	16 Mar 2021 15:03:27

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '16 Mar 2021'	Carlton Griffin (b) (4)	16 Mar 2021 15:03:27

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'Clinic (Clinic)'	Carlton Griffin (b) (4)	16 Mar 2021 15:03:27

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User entered 'VISIT4'	System	16 Mar 2021 15:03:27

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'No (N)'	Carlton Griffin (b) (4)	30 Mar 2021 14:51:03

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered empty.	Carlton Griffin (b) (4)	30 Mar 2021 14:51:03

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered empty.	Carlton Griffin (b) (4)	30 Mar 2021 14:51:03

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User entered empty.	System	30 Mar 2021 14:51:03



**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered empty.	Carlton Griffin (b) (4)	30 Mar 2021 14:51:03

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered empty.	Carlton Griffin (b) (4)	30 Mar 2021 14:51:03

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered empty.	Carlton Griffin (b) (4)	30 Mar 2021 14:51:03

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered empty.	Carlton Griffin (b) (4)	30 Mar 2021 14:51:03

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User entered empty.	System	30 Mar 2021 14:51:03

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered empty.	Carlton Griffin (b) (4)	30 Mar 2021 14:51:03

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User entered empty.	System	30 Mar 2021 14:51:03

US3782100

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:43:22

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered empty.	Carlton Griffin (b) (4)	30 Mar 2021 14:51:03



**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User entered empty.	System	30 Mar 2021 14:51:03

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered empty.	Carlton Griffin (b) (4)	30 Mar 2021 14:51:03

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User entered empty.	System	30 Mar 2021 14:51:03

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:43:22**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	16 Mar 2021 15:03:54

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:43:22**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '16 Mar 2021'	Carlton Griffin (b) (4)	16 Mar 2021 15:03:54

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:43:22**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	16 Mar 2021 15:03:38



**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:43:22**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '16 Mar 2021'	Carlton Griffin (b) (4)	16 Mar 2021 15:03:38

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:43:22**

**Collection time (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '10:01'	Carlton Griffin (b) (4)	16 Mar 2021 15:03:38

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:43:22**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User entered '16 Mar 2021 10:01'	System	16 Mar 2021 15:03:38

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	16 Mar 2021 15:03:44

**US3782100**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:30:18
User entered 'I'	System	16 Mar 2021 15:03:44

**US3782100**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:00
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	21 Apr 2021 15:46:56
	(b) (4)	

**US3782100**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:00
	(b) (4)	
User entered '21 Apr 2021'	Carlton Griffin (b) (4)	21 Apr 2021 15:46:56
	(b) (4)	

**US3782100**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:00
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	21 Apr 2021 15:46:56



**US3782100**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	28 Apr 2021 21:43:00
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	21 Apr 2021 15:46:56
	(b) (4)	

**US3782100**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	28 Apr 2021 21:43:00
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	21 Apr 2021 15:47:00

**US3782100**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 15:47:00

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:10:52

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '5 Jan 2021'	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:10:52

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[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 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Clinic (Clinic)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	05 Jan 2021 15:10:52

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'UNBLND_DECIDE'	System	05 Jan 2021 15:10:52

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:43:22**

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '5 Jan 2021'	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:11:07



**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:43:22**

[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 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 17:47:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:43:22**

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:11:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:43:22**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
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 17:47:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:43:22**

**Date of unblinding (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '5 Jan 2021'	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:11:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:43:22**

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Placebo (Placebo)'	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:11:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:43:22**

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 13:08:28
User entered 'Placebo (Placebo)'	Carlton Griffin (b) (4)	05 Jan 2021 15:11:07
	(b) (4)	

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:43:22**

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4)	20 Jan 2021 13:08:28
User entered 'Placebo (Placebo)'	Carlton Griffin (b) (4)	05 Jan 2021 15:11:07
	(b) (4)	

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:43:22**

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:11:07



**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:43:22**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'I'	System	05 Jan 2021 15:11:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:43:22**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'I'	System	05 Jan 2021 15:11:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:43:22**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '158.0' cm	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:12:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:43:22**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '51.2' kg	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:12:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:43:22**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered '20.50953'	System	05 Jan 2021 15:12:07
DataPoint set to visible.	System	05 Jan 2021 15:11:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:43:22**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '158.0' cm	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:12:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:43:22**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '51.2' kg	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:12:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:43:22**

**BMI (xxx.x)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered '20.50953'	System	05 Jan 2021 15:12:07
DataPoint set to visible.	System	05 Jan 2021 15:11:07



**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User accepted default value 'Pre-Dose (PREDOSE)'	Carlton Griffin (b) (4) (b) (4)	05 Jan 2021 15:12:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:12:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '5 Jan 2021'	(b) (4) Carlton Griffin (b) (4) (b) (4)	05 Jan 2021 15:12:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '09:01'	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:12:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered '5 Jan 2021 09:01'	System	05 Jan 2021 15:12:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '98.5' F	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:12:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Oral (Oral)'	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:12:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered empty.	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:12:07



**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '75'	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:12:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'bpm'	System	05 Jan 2021 15:12:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '16'	(b) (4) Carlton Griffin (b) (4) (b) (4)	05 Jan 2021 15:12:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'breaths/min'	System	05 Jan 2021 15:12:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '137'	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:12:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'mmHg'	System	05 Jan 2021 15:12:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '88'	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:12:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'mmHg'	System	05 Jan 2021 15:12:07



**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:43:22**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '158.0' cm	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:12:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:43:22**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '51.2' kg	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:12:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing**

**Generated On: 10 Jun 2021 09:43:22**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered '20.50953'	System	05 Jan 2021 15:12:07
DataPoint set to visible.	System	05 Jan 2021 15:11:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User accepted default value 'Post-Dose (POSTDOSE)'	Trudy Sullivan (b) (4) (b) (4)	05 Jan 2021 17:19:17

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4) Trudy Sullivan (b) (4)	05 Jan 2021 17:19:17

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '5 Jan 2021'	Trudy Sullivan (b) (4)	05 Jan 2021 17:19:17

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '10:00'	Trudy Sullivan (b) (4)	05 Jan 2021 17:19:17

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered '5 Jan 2021 10:00'	System	05 Jan 2021 17:19:17



**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '97.6' F	(b) (4) Trudy Sullivan (b) (4)	05 Jan 2021 17:19:17

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Oral (Oral)'	(b) (4) Trudy Sullivan (b) (4)	05 Jan 2021 17:19:17

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered empty.	(b) (4) Trudy Sullivan (b) (4)	05 Jan 2021 17:19:17

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '82'	Trudy Sullivan (b) (4)	05 Jan 2021 17:19:17

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'bpm'	System	05 Jan 2021 17:19:17

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '18'	Trudy Sullivan (b) (4)	05 Jan 2021 17:19:17

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'breaths/min'	System	05 Jan 2021 17:19:17

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '120'	Trudy Sullivan (b) (4)	05 Jan 2021 17:19:17



**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'mmHg'	System	05 Jan 2021 17:19:17

US3782100

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	06 Jan 2021 12:40:27
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Carlton Griffin (b) (4) (b) (4)	05 Jan 2021 18:14:57
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		05 Jan 2021 17:19:17
User entered '55'	Trudy Sullivan (b) (4) (b) (4)	05 Jan 2021 17:19:17

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'mmHg'	System	05 Jan 2021 17:19:17

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:43:22**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:11:15

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:43:22**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '5 Jan 2021'	Carlton Griffin (b) (4)	05 Jan 2021 15:11:15

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:35:31

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:35:31

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

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 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:35:31



**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'mRNA-1273'	System	05 Jan 2021 15:35:31
DataPoint set to visible.	System	05 Jan 2021 15:11:07

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '5 Jan 2021'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:35:31

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '09:28'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:35:31

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered '5 Jan 2021 09:28'	System	05 Jan 2021 15:35:31

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	05 Jan 2021 15:35:31

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'ONCE'	System	05 Jan 2021 15:35:31

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'INTRAMUSCULAR'	System	05 Jan 2021 15:35:31

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:43:22**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:12:23



US3782100

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:22

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
Query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 05JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 05JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate.' canceled (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 13:01:45
User opened query 'Per GCL Lab Reconciliation: Immunogenicity Assessment: Per GCL, there is an Immunogenicity Assessment sample collected on 05JAN2020 for the Participant Decision Visit, however, the Collection Date recorded here is 05JAN2021. Please confirm the correct Collection Date in the query response and update if appropriate.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 17:55:15
User entered '5 Jan 2021'	Carlton Griffin (b) (4)	05 Jan 2021 15:12:23

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:43:22**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '08:56'	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:12:23

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:43:22**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered '5 Jan 2021 08:56'	System	05 Jan 2021 15:12:23

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:43:22**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:12:34

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:43:22**

[Collection date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '5 Jan 2021'	Carlton Griffin (b) (4)	05 Jan 2021 15:12:34

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:43:22**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '08:58'	(b) (4) Carlton Griffin (b) (4) (b) (4)	05 Jan 2021 15:12:34

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:43:22**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered '5 Jan 2021 08:58'	System	05 Jan 2021 15:12:34

**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	05 Jan 2021 15:12:40



**US3782100**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'I'	System	05 Jan 2021 15:12:40

**US3782100**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:56:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	12 Jan 2021 14:22:34

**US3782100**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:56:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered '12 Jan 2021'	Carlton Griffin (b) (4)	12 Jan 2021 14:22:34

**US3782100**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:56:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Contact Made (CONTACT MADE)'	Carlton Griffin (b) (4)	12 Jan 2021 14:22:34

**US3782100**

**Folder: Safety Call OL-D8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:56:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered empty.	Carlton Griffin (b) (4)	12 Jan 2021 14:22:34

**US3782100**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:56:11
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:57
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	12 Jan 2021 14:22:40

**US3782100**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:56:11
User entered 'I'	System	12 Jan 2021 14:22:40

**US3782100**

**Folder: Safety Call OL-D8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 13:56:11
User entered '1'	System	12 Jan 2021 14:22:40
DataPoint set to visible.	System	12 Jan 2021 14:22:40



**US3782100**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:42

**US3782100**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:42

**US3782100**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[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 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:42

**US3782100**

**Folder: OL-D29 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'OLD29'	System	02 Feb 2021 16:05:42

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	02 Feb 2021 16:02:43

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:02:43

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:02:43

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered '08:50'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:02:43



**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered '2 Feb 2021 08:50'	System	02 Feb 2021 16:02:43

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered '97.6' F	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:02:43

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:02:43

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:02:43

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered '72'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:02:43

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'bpm'	System	02 Feb 2021 16:02:43

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered '16'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:02:43

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'breaths/min'	System	02 Feb 2021 16:02:43



**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered '129'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:02:43

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'mmHg'	System	02 Feb 2021 16:02:43

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered '78'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:02:43

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'mmHg'	System	02 Feb 2021 16:02:43

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Feb 2021 16:03:14

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:03:14

US3782100

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:43:22

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:03:14

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

**Time of assessment (00:00-23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered '09:40'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:03:14



**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered '2 Feb 2021 09:40'	System	02 Feb 2021 16:03:14

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered '97.5' F	(b) (4), (b) (6)	02 Feb 2021 16:03:14

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:03:14

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 16:03:14

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered '72'	(b) (4), (b) (6)	02 Feb 2021 16:03:14

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'bpm'	System	02 Feb 2021 16:03:14

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered '16'	(b) (4), (b) (6)	02 Feb 2021 16:03:14

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'breaths/min'	System	02 Feb 2021 16:03:14



**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered '129'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:03:14

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'mmHg'	System	02 Feb 2021 16:03:14

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered '78'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:03:14

**US3782100**

**Folder: OL-D29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'mmHg'	System	02 Feb 2021 16:03:14

**US3782100**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:43:22**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:50

**US3782100**

**Folder: OL-D29 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:43:22**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:50

**US3782100**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:06:14

**US3782100**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered empty.	(b) (4), (b) (6)	02 Feb 2021 16:06:14



**US3782100**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

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 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:06:14

**US3782100**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'mRNA-1273'	System	02 Feb 2021 16:06:14
DataPoint set to visible.	System	12 Jan 2021 14:22:40

**US3782100**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered '2 Feb 2021'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:06:14

**US3782100**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered '09:10'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:06:14

**US3782100**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered '2 Feb 2021 09:10'	System	02 Feb 2021 16:06:14

**US3782100**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:06:14

**US3782100**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'ONCE'	System	02 Feb 2021 16:06:14

**US3782100**

**Folder: OL-D29 (1)**

**Form: Exposure**

**Generated On: 10 Jun 2021 09:43:22**

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'INTRAMUSCULAR'	System	02 Feb 2021 16:06:14



**US3782100**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Feb 2021 16:05:56

**US3782100**

**Folder: OL-D29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:36:26
User entered 'I'	System	02 Feb 2021 16:05:56

**US3782100**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:27:12
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 16:16:02

**US3782100**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:27:12
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 16:16:02

**US3782100**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:27:12
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 16:16:02

**US3782100**

**Folder: Safety Call OL-D36 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:43:22**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:27:12
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 16:16:02

**US3782100**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:27:12
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:29:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 16:16:10

**US3782100**

**Folder: Safety Call OL-D36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:43:22**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:27:12
User entered 'I'	System	09 Feb 2021 16:16:10



**US3782100**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	16 Mar 2021 15:02:10
	(b) (4)	

**US3782100**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
	(b) (4)	
User entered '16 Mar 2021'	Carlton Griffin (b) (4)	16 Mar 2021 15:02:10
	(b) (4)	

**US3782100**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
	(b) (4)	
User entered 'Clinic (Clinic)'	Carlton Griffin (b) (4)	16 Mar 2021 15:02:10
	(b) (4)	

**US3782100**

**Folder: OL-D57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:43:22**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User entered 'OLD57'	System	16 Mar 2021 15:02:10

**US3782100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	16 Mar 2021 15:02:17
	(b) (4)	

**US3782100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

**Date of assessment** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	16 Mar 2021 15:02:17
	(b) (4)	

**US3782100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	16 Mar 2021 15:02:17
	(b) (4)	

**US3782100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User entered empty.	System	16 Mar 2021 15:02:17



**US3782100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Temperature \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	16 Mar 2021 15:02:17
	(b) (4)	

**US3782100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	16 Mar 2021 15:02:17
	(b) (4)	

**US3782100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	16 Mar 2021 15:02:17
	(b) (4)	

**US3782100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	16 Mar 2021 15:02:17
	(b) (4)	

**US3782100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User entered empty.	System	16 Mar 2021 15:02:17

**US3782100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	16 Mar 2021 15:02:17
	(b) (4)	

**US3782100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User entered empty.	System	16 Mar 2021 15:02:17

**US3782100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	16 Mar 2021 15:02:17
	(b) (4)	



**US3782100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User entered empty.	System	16 Mar 2021 15:02:17

**US3782100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	16 Mar 2021 15:02:17
	(b) (4)	

**US3782100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User entered empty.	System	16 Mar 2021 15:02:17

**US3782100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43

**US3782100**

**Folder: OL-D57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:43:22**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43

**US3782100**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:43:22**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	16 Mar 2021 15:02:44
	(b) (4)	

**US3782100**

**Folder: OL-D57 (1)**

**Form: Physical Examination**

**Generated On: 10 Jun 2021 09:43:22**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
	(b) (4)	
User entered '16 Mar 2021'	Carlton Griffin (b) (4)	16 Mar 2021 15:02:44
	(b) (4)	

**US3782100**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:43:22**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	16 Mar 2021 15:03:14
	(b) (4)	



US3782100

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:43:22

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
	(b) (4)	
User entered '16 Mar 2021'	Carlton Griffin (b) (4)	16 Mar 2021 15:03:14
	(b) (4)	

**US3782100**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:43:22**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
	(b) (4)	
User entered '10:01'	Carlton Griffin (b) (4)	16 Mar 2021 15:03:14
	(b) (4)	

**US3782100**

**Folder: OL-D57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:43:22**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:50:43
User entered '16 Mar 2021 10:01'	System	16 Mar 2021 15:03:14

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 10 Jun 2021 09:43:22**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:06
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:38
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 17:16:13

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 20:34:28
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:26
User entered		
'USA-US125-2020-mRNA-1273-P301000012'	System	05 Dec 2020 16:26:22
User entered 'New'	(b) (4), (b) (6)	05 Dec 2020 16:26:22

US3782100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:22

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 20:34:31
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Duodenal and small intestinal stenosis and obstruction, PT: Small intestinal obstruction, LLT: Small bowel obstruction - version MedDRA\\23.0.	Coder Import (b) (4)	04 Dec 2020 17:23:58
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Dec 2020 17:23:58
	(b) (4)	
Data point term sent to Coder	System	04 Dec 2020 17:23:09
User entered 'small bowel obstruction'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:34:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:34:41
User entered 'No (N)'	(b) (4), (b) (6)	04 Dec 2020 17:22:18



**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:34:46
User entered 'No (N)'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:34:48
User entered '29 Nov 2020'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:34:52
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:34:55
User entered 'No (N)'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

*If not Ongoing, end date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:34:57
User entered '2 Dec 2020'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:35:03
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Dec 2020 17:22:18



**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:35:06
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:35:11
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:35:27
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:35:27
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:35:27
User entered 'I'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

**Hospital Admission Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:35:27
User entered '30 Nov 2020'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

**Hospital Discharge Date (dd MMM yyyy)**

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:35:27
User entered '04 Dec 2020'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:35:27
User entered 'No (N)'	(b) (4), (b) (6)	04 Dec 2020 17:22:18



**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:35:27
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:35:27
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 20:35:27
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:35:27
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:35:27
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:35:27
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:35:27
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 20:35:27
User entered '0'	(b) (4), (b) (6)	04 Dec 2020 17:22:18



**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:35:27
User entered 'I'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:35:27
User entered 'I'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 20:35:27
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	07 Dec 2020 19:56:33
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[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 20:19:52
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 20:35:27
User entered empty; reason for change New Information	(b) (4), (b) (6)	07 Dec 2020 19:56:33
User entered 'post op pain'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

US3782100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:22

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:35:27
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 14:29:30
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 14:29:21
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'sent' (Site from Safety).	Carlton Griffin (b) (4)	14 Dec 2020 19:07:32
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'nasopharyngeal swab on 01-dec-2020 resulted negative' (Site from Safety).	Carlton Griffin (b) (4)	14 Dec 2020 15:01:49
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 23:07:10
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	10 Dec 2020 23:07:04

US3782100

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:43:22

[Narrative](#)

Audit	User	Time (GMT)
User entered '04DEC2020 Spoke to participant's husband today.  29NOV2020 He states participant began experiencing abdominal pain.  30NOV2020 Pain continued and they went to the emergency room at St. Thomas West. Participant had a CT scan that revealed a blockage in her lower intestine, and she was admitted that evening.  01DEC2020 Participant's husband reports NG tube was placed.  02DEC2020 Participant's husband reports she underwent successful laparoscopic removal of adhesions (related to previous abdominal surgery) to treat her small bowel obstruction.  Currently they are awaiting discharge and her diet is progressing to solids. We will plan to obtain a copy of her medical records post discharge. Added AE/SAE and con procedures but will await medical records for medication details'	(b) (4), (b) (6)	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Dec 2020 17:22:18

**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Dec 2020 17:22:18



**US3782100**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Dec 2020 17:22:18

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 10 Jun 2021 09:43:22**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:06
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:46:34
User entered 'Yes (Y)'	Amber Massey (b) (4) (b) (4)	27 Aug 2020 18:34:51

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:43:22

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ROSUVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Aug 2020 19:49:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:49:12
Data point term sent to Coder	System	27 Aug 2020 18:36:39
User entered 'rosuvastatin'	Amber Massey (b) (4) (b) (4)	27 Aug 2020 18:35:40

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'No (N)'	Amber Massey (b) (4)	27 Aug 2020 18:35:40
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'hypercholesterolemia'	Amber Massey (b) (4)	27 Aug 2020 18:35:40
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered '5'	Amber Massey (b) (4)	27 Aug 2020 18:35:40
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'mg (mg)'	Amber Massey (b) (4)	27 Aug 2020 18:35:40
	(b) (4)	

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:43:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:19:52
User entered empty.	Amber Massey (b) (4) (b) (4)	27 Aug 2020 18:35:40



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'once daily (QD)'	Amber Massey (b) (4)	27 Aug 2020 18:35:40
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:43:22**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:19:52
User entered empty.	Amber Massey (b) (4) (b) (4)	27 Aug 2020 18:35:40

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Massey (b) (4)	27 Aug 2020 18:35:40
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:43:22**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered empty.	Amber Massey (b) (4)	27 Aug 2020 18:35:40
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'un UNK 2015'	Amber Massey (b) (4)	27 Aug 2020 18:35:40
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered '0'	Amber Massey (b) (4)	27 Aug 2020 18:35:40
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'Yes (Y)'	Amber Massey (b) (4)	27 Aug 2020 18:35:40
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:43:22**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered empty.	Amber Massey (b) (4)	27 Aug 2020 18:35:40
	(b) (4)	



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'No (N)'	Amber Massey (b) (4)	27 Aug 2020 18:35:40
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 18:35:40

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 18:35:40

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 18:35:40

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:43:22

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: BIOTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Aug 2020 19:49:12
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:49:12
Data point term sent to Coder	System	27 Aug 2020 18:36:40
User entered 'Biotin'	Amber Massey (b) (4) (b) (4)	27 Aug 2020 18:36:12

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'No (N)'	Amber Massey (b) (4)	27 Aug 2020 18:36:12
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'General health'	Amber Massey (b) (4)	27 Aug 2020 18:36:12
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered '1'	Amber Massey (b) (4)	27 Aug 2020 18:36:12
	(b) (4)	



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'capsule (CAPSULE)'	Amber Massey (b) (4)	27 Aug 2020 18:36:12
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:43:22**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:19:52
User entered empty.	Amber Massey (b) (4) (b) (4)	27 Aug 2020 18:36:12

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'once daily (QD)'	Amber Massey (b) (4)	27 Aug 2020 18:36:12
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:43:22**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered empty.	Amber Massey (b) (4)	27 Aug 2020 18:36:12
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Massey (b) (4)	27 Aug 2020 18:36:12
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:43:22**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered empty.	Amber Massey (b) (4)	27 Aug 2020 18:36:12
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'un UNK 2016'	Amber Massey (b) (4)	27 Aug 2020 18:36:12
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered '0'	Amber Massey (b) (4)	27 Aug 2020 18:36:12
	(b) (4)	



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'Yes (Y)'	Amber Massey (b) (4)	27 Aug 2020 18:36:12
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:43:22**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered empty.	Amber Massey (b) (4)	27 Aug 2020 18:36:12
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'No (N)'	Amber Massey (b) (4)	27 Aug 2020 18:36:12
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 18:36:12

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 18:36:12

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 18:36:12

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:43:22

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Aug 2020 19:49:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:49:20
Data point term sent to Coder	System	27 Aug 2020 18:38:44
User entered 'vitamin D'	Amber Massey (b) (4) (b) (4)	27 Aug 2020 18:38:11

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:43:22**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'No (N)'	Amber Massey (b) (4)	27 Aug 2020 18:38:11
	(b) (4)	



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:43:22**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'general health'	Amber Massey (b) (4)	27 Aug 2020 18:38:11
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered '2000'	Amber Massey (b) (4)	27 Aug 2020 18:38:11
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'IU (IU)'	Amber Massey (b) (4)	27 Aug 2020 18:38:11
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:43:22**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:19:52
User entered empty.	Amber Massey (b) (4) (b) (4)	27 Aug 2020 18:38:11

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:43:22**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'once daily (QD)'	Amber Massey (b) (4)	27 Aug 2020 18:38:11
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:43:22**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered empty.	Amber Massey (b) (4)	27 Aug 2020 18:38:11
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:43:22**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Massey (b) (4)	27 Aug 2020 18:38:11
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:43:22**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered empty.	Amber Massey (b) (4)	27 Aug 2020 18:38:11
	(b) (4)	



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'un UNK 2016'	Amber Massey (b) (4)	27 Aug 2020 18:38:11
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered '0'	Amber Massey (b) (4)	27 Aug 2020 18:38:11
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:43:22**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'Yes (Y)'	Amber Massey (b) (4)	27 Aug 2020 18:38:11
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:43:22**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered empty.	Amber Massey (b) (4)	27 Aug 2020 18:38:11
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:43:22**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'No (N)'	Amber Massey (b) (4)	27 Aug 2020 18:38:11
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:43:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 18:38:11

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 18:38:11

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 18:38:11



US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:43:22

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	28 Aug 2020 11:54:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 11:54:41
Data point term sent to Coder	System	27 Aug 2020 18:39:47
User entered 'magnesium'	Amber Massey (b) (4) (b) (4)	27 Aug 2020 18:38:54

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:43:22**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'No (N)'	Amber Massey (b) (4)	27 Aug 2020 18:38:54
	(b) (4)	

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:43:22

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User closed query 'Per DM CLR: Please update the indication to reflect the laterality of LEG SPASMS. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:04:54
Query 'Per DM CLR: Please update the indication to reflect the laterality of LEG SPASMS. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'not clinically significant ' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	28 Oct 2020 16:23:12
User opened query 'Per DM CLR: Please update the indication to reflect the laterality of LEG SPASMS. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 20:56:13
User entered 'leg spasms'	Amber Massey (b) (4) (b) (4)	27 Aug 2020 18:38:54

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered '1250'	Amber Massey (b) (4)	27 Aug 2020 18:38:54
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'mg (mg)'	Amber Massey (b) (4)	27 Aug 2020 18:38:54
	(b) (4)	

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:43:22

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered empty.	Amber Massey (b) (4)	27 Aug 2020 18:38:54
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:43:22**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'once daily (QD)'	Amber Massey (b) (4)	27 Aug 2020 18:38:54
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:43:22**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered empty.	Amber Massey (b) (4)	27 Aug 2020 18:38:54
	(b) (4)	



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:43:22**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'Oral (ORAL)'	Amber Massey (b) (4)	27 Aug 2020 18:38:54
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:43:22**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered empty.	Amber Massey (b) (4)	27 Aug 2020 18:38:54
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'un Jan 2020'	Amber Massey (b) (4)	27 Aug 2020 18:38:54
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered '0'	Amber Massey (b) (4)	27 Aug 2020 18:38:54
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:43:22**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'Yes (Y)'	Amber Massey (b) (4)	27 Aug 2020 18:38:54
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:43:22**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered empty.	Amber Massey (b) (4)	27 Aug 2020 18:38:54
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:43:22**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'No (N)'	Amber Massey (b) (4)	27 Aug 2020 18:38:54
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:43:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 18:38:54



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	27 Aug 2020 18:38:54

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 18:38:54

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:43:22

Name of Medication

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening LEG SPASMS should be recorded, and update con med indication or provide clarification. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	29 Jan 2021 14:24:13
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening LEG SPASMS should be recorded, and update con med indication or provide clarification. ' answered with 'not added because the MH condition worsened per vol' (Site from DM).	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening LEG SPASMS should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OTHER ANTIINFLAMMATORY AND ANTIRHEUMATIC AGENTS, NON-STEROIDS, PRODUCT: GLUCOSAMINE - version WHODrug-Global-B3\\202003.	Carlton Griffin (b) (4)	12 Jan 2021 14:54:36
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	(b) (4), (b) (6)	02 Jan 2021 19:36:28
User entered 'glucosamine'	Coder Import (b) (4)	22 Oct 2020 15:09:40
	(b) (4)	
	Coder Import (b) (4)	22 Oct 2020 15:09:40
	(b) (4)	
	System	22 Oct 2020 12:59:03
	Carlton Griffin (b) (4)	22 Oct 2020 12:58:02
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:43:22**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	22 Oct 2020 12:58:02
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:43:22**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'leg spasms'	Carlton Griffin (b) (4)	22 Oct 2020 12:58:02
	(b) (4)	

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:43:22

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 20:25:32
User entered '1500' reason for change: Data Entry Error	Carlton Griffin (b) (4)	12 Jan 2021 14:58:12
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4)	
User entered '1250'	Carlton Griffin (b) (4)	12 Jan 2021 14:58:04
	(b) (4)	
	(b) (4), (b) (6)	02 Jan 2021 19:37:05
	Carlton Griffin (b) (4)	22 Oct 2020 12:58:02
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	22 Oct 2020 12:58:02
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:43:22**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	22 Oct 2020 12:58:02
	(b) (4)	



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:43:22**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'once daily (QD)'	Carlton Griffin (b) (4)	22 Oct 2020 12:58:02
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:43:22**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	22 Oct 2020 12:58:02
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:43:22**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'Oral (ORAL)'	Carlton Griffin (b) (4)	22 Oct 2020 12:58:02
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:43:22**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	22 Oct 2020 12:58:02
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered '15 Oct 2020'	Carlton Griffin (b) (4)	22 Oct 2020 12:58:02
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	22 Oct 2020 12:58:02
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:43:22**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	22 Oct 2020 12:58:02
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:43:22**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	22 Oct 2020 12:58:02
	(b) (4)	



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:43:22**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	22 Oct 2020 12:58:02
	(b) (4)	

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:43:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 12:58:02

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 12:58:02

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 12:58:02

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:22

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:07
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 12:59:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 12:59:30
Data point term sent to Coder	System	22 Oct 2020 12:59:03
User entered 'influenza vaccine'	Carlton Griffin (b) (4)	22 Oct 2020 12:58:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:43:22**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:07
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 12:58:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:43:22**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:07
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'influenza prophylaxis'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Oct 2020 12:58:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:07
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '0.5'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 12:58:36



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:07
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'mL (mL)'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 12:58:36

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:07
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered empty.	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 12:58:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:43:22**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:07
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'once (ONCE)'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 12:58:36

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:07
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered empty.	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 12:58:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:43:22**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:07
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 12:58:36

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:43:22

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:07
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered empty.	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 12:58:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:07
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '17 Oct 2020'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 12:58:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:07
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '0'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 12:58:36



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:43:22**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:07
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 12:58:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:43:22**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:07
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '17 Oct 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Oct 2020 12:58:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:43:22**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:07
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 12:58:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:43:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:07
User entered empty.	System	22 Oct 2020 12:58:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:07
User entered empty.	System	22 Oct 2020 12:58:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:07
User entered empty.	System	22 Oct 2020 12:58:36

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:43:22

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:13
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE POLYSACCH 23V, PRODUCTSYNONYM: PNEUMOVAX 23 - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Oct 2020 16:33:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 16:33:45
Data point term sent to Coder	System	22 Oct 2020 13:01:06
User entered 'pneumovax23'	Carlton Griffin (b) (4) (b) (4)	22 Oct 2020 13:00:30

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:43:22**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:13
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Oct 2020 13:00:30



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:43:22**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:13
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'pneumococcal prophylaxis'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 13:00:30

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:13
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '0.5'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 13:00:30

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:13
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'mL (mL)'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 13:00:30

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:43:22**

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:13
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered empty.	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 13:00:30

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:43:22**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:13
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'once (ONCE)'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 13:00:30

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:43:22**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:13
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered empty.	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 13:00:30

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:43:22**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:13
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 13:00:30

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:43:22**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:13
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered empty.	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 13:00:30



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:13
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '17 Oct 2020'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 13:00:30

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:13
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '0'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Oct 2020 13:00:30

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:43:22**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:13
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 13:00:30

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:43:22**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:13
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '17 Oct 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Oct 2020 13:00:30

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:43:22**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:13
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	22 Oct 2020 13:00:30

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:43:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:13
User entered empty.	System	22 Oct 2020 13:00:30

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:13
User entered empty.	System	22 Oct 2020 13:00:30

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:13
User entered empty.	System	22 Oct 2020 13:00:30



US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:43:22

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:44:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 06:34:45
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 06:34:45
Data point term sent to Coder	System	07 Dec 2020 19:49:13
User entered 'zofran'	(b) (4), (b) (6)	07 Dec 2020 19:48:35

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:43:22**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:44:20
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 19:48:35

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:43:22**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:44:22
User entered 'small bowel obstruction'	(b) (4), (b) (6)	07 Dec 2020 19:48:35

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:44:26
User entered '8'	(b) (4), (b) (6)	07 Dec 2020 19:48:35

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:44:28
User entered 'mg (mg)'	(b) (4), (b) (6)	07 Dec 2020 19:48:35

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:43:22**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:44:30
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:48:35

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:43:22**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:44:31
User entered 'once (ONCE)'	(b) (4), (b) (6)	07 Dec 2020 19:48:35

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:43:22**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:44:34
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:48:35



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:43:22**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:44:36
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	07 Dec 2020 19:48:35

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:43:22**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:44:37
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:48:35

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:44:40
User entered '30 Nov 2020'	(b) (4), (b) (6)	07 Dec 2020 19:48:35

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:44:42
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 19:48:35

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:43:22**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:44:44
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 19:48:35

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:43:22**

**If not Ongoing, End date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:44:47
User entered '30 Nov 2020'	(b) (4), (b) (6)	07 Dec 2020 19:48:35

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:43:22**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:19
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:44:49
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 19:48:35

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:43:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:19
User entered empty.	System	07 Dec 2020 19:48:35



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:19
User entered empty.	System	07 Dec 2020 19:48:35

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:19
User entered empty.	System	07 Dec 2020 19:48:35

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:43:22

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:44:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ANESTHETICS, GENERAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 20:06:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 20:06:54
Data point term sent to Coder	System	07 Dec 2020 19:50:14
User entered 'general anesthesia'	(b) (4), (b) (6)	07 Dec 2020 19:50:08

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:43:22**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:44:58
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 19:50:08

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:43:22**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:44:59
User entered 'small bowel obstruction'	(b) (4), (b) (6)	07 Dec 2020 19:50:08

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:45:02
User entered 'unknown'	(b) (4), (b) (6)	07 Dec 2020 19:50:08

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:45:05
User entered 'Other (OTHER)'	(b) (4), (b) (6)	07 Dec 2020 19:50:08

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:43:22**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:45:07
User entered 'unknown'	(b) (4), (b) (6)	07 Dec 2020 19:50:08



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:43:22**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:45:08
User entered 'unknown (UNKNOWN)'	(b) (4), (b) (6)	07 Dec 2020 19:50:08

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:43:22**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:45:10
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:50:08

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:43:22**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:45:12
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	07 Dec 2020 19:50:08

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:43:22**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:45:14
User entered empty.	(b) (4), (b) (6)	07 Dec 2020 19:50:08

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:45:16
User entered '2 Dec 2020'	(b) (4), (b) (6)	07 Dec 2020 19:50:08

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:45:17
User entered '0'	(b) (4), (b) (6)	07 Dec 2020 19:50:08

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:43:22**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:45:19
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 19:50:08

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:43:22**

**If not Ongoing, End date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:45:20
User entered '2 Dec 2020'	(b) (4), (b) (6)	07 Dec 2020 19:50:08



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:43:22**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:32
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:45:22
User entered 'No (N)'	(b) (4), (b) (6)	07 Dec 2020 19:50:08

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:43:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:32
User entered empty.	System	07 Dec 2020 19:50:08

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:32
User entered empty.	System	07 Dec 2020 19:50:08

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:32
User entered empty.	System	07 Dec 2020 19:50:08

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:43:22

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: ENOXAPARIN SODIUM, PRODUCTSYNONYM: LOVENOX [ENOXAPARIN SODIUM] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Dec 2020 01:35:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 01:35:54
Data point term sent to Coder	System	07 Dec 2020 19:52:16
User entered 'lovenox'	(b) (4), (b) (6)	07 Dec 2020 19:51:43

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:43:22**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:51:43

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:43:22**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'deep vein thrombosis prophylaxis'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:51:43

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '40'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:51:43



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:51:43

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:43:22**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:51:43

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:43:22**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:51:43

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:43:22**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:51:43

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:43:22**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:51:43

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:43:22**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:51:43

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '2 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:51:43

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '0'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:51:43



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:43:22**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:51:43

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:43:22**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered '4 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:51:43

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:43:22**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:43
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	07 Dec 2020 19:51:43

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:43:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:43
User entered '1'	System	07 Dec 2020 19:51:43

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:43
User entered '1'	System	07 Dec 2020 19:51:43

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:43
User entered '804 (804)'	System	07 Dec 2020 19:51:43

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:22

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ANESTHETICS, GENERAL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 08:11:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Mar 2021 08:11:55
Data point term sent to Coder	System	02 Mar 2021 15:15:33
User closed query 'DM-Coding: This medication cannot be referenced as reported. Please enter a trade name with the generic/active ingredient(s) in the drug name field. Please make your changes to the reported term.' (Site from System).	System	02 Mar 2021 15:15:27
Query 'DM-Coding: This medication cannot be referenced as reported. Please enter a trade name with the generic/active ingredient(s) in the drug name field. Please make your changes to the reported term.' answered with 'trade name and generic/active ingredients not reported ' (Site from System).	Carlton Griffin (b) (4)	02 Mar 2021 15:15:27
User opened query 'DM-Coding: This medication cannot be referenced as reported. Please enter a trade name with the generic/active ingredient(s) in the drug name field. Please make your changes to the reported term.' (Site from System).	Coder Import (b) (4)	02 Mar 2021 11:19:45
Data point term sent to Coder	System	22 Feb 2021 16:16:50
User entered 'general anesthesia'	Carlton Griffin (b) (4)	22 Feb 2021 16:16:03

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:43:22**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:16:03



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:43:22**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'neck lift'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:16:03

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'unknown'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:16:03

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'Other (OTHER)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:16:03

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'unknown'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:16:03

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:43:22**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'unknown (UNKNOWN)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Feb 2021 16:16:03

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:43:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered empty.	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:16:03

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:43:22**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:16:03

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:43:22**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered empty.	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:16:03



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '11 Feb 2021'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:16:03

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '0'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Feb 2021 16:16:03

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:43:22**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:16:03

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:43:22**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '11 Feb 2021'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Feb 2021 16:16:03

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:43:22**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:47
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:16:03

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:43:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:47
User entered empty.	System	22 Feb 2021 16:16:03

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:47
User entered empty.	System	22 Feb 2021 16:16:03

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:47
User entered empty.	System	22 Feb 2021 16:16:03



US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:22

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 18:29:00
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 18:29:00
Data point term sent to Coder	System	22 Feb 2021 16:23:59
User entered 'clindamcyin'	Carlton Griffin (b) (4)	22 Feb 2021 16:23:16

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:43:22**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:23:16

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:43:22**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'infection prophylaxis post neck lift'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Feb 2021 16:23:16

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '300'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:23:16

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'mg (mg)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:23:16

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered empty.	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Feb 2021 16:23:16

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:43:22**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'three times daily (TID)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:23:16

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:43:22

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered empty.	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:23:16



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:43:22**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'Oral (ORAL)'	Carlton Griffin (b) (4)	22 Feb 2021 16:23:16

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:43:22**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered empty.	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:23:16

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '11 Feb 2021'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:23:16

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '0'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Feb 2021 16:23:16

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:43:22**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:23:16

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:43:22**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '16 Feb 2021'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Feb 2021 16:23:16

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:43:22**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:54
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:23:16

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:43:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:54
User entered '3'	System	22 Feb 2021 16:23:16



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:54
User entered '1'	System	22 Feb 2021 16:23:16

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:04:54
User entered '804 (804)'	System	22 Feb 2021 16:23:16

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:43:22

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:00
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 16:26:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 16:26:59
Data point term sent to Coder	System	22 Feb 2021 16:26:01
User entered 'hydrocodone/acetaminophen'	Carlton Griffin (b) (4)	22 Feb 2021 16:25:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:43:22**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:00
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:25:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:43:22**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:00
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'post-op pain neck lift'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Feb 2021 16:25:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:00
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '7.5/325'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:25:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:00
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'mg (mg)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:25:36

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:43:22

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:00
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered empty.	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:25:36



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:43:22**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:00
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'as needed (PRN)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:25:36

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:43:22

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:00
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered empty.	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:25:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:43:22**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:00
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'Oral (ORAL)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:25:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:43:22**

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:00
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered empty.	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:25:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:00
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '11 Feb 2021'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:25:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:00
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '0'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Feb 2021 16:25:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:43:22**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:00
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:25:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:43:22**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:00
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '16 Feb 2021'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Feb 2021 16:25:36



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:43:22**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:00
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:25:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:43:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:00
User entered empty.	System	22 Feb 2021 16:25:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:00
User entered empty.	System	22 Feb 2021 16:25:36

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:00
User entered empty.	System	22 Feb 2021 16:25:36

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:43:22

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:05
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Feb 2021 16:27:59
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Feb 2021 16:27:59
Data point term sent to Coder	System	22 Feb 2021 16:27:02
User entered 'tylenol'	Carlton Griffin (b) (4) (b) (4)	22 Feb 2021 16:26:50

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:43:22**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:05
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:26:50

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:43:22**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:05
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'post-op pain neck lift'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:26:50

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:05
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '1000'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:26:50



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:43:22**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:05
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'mg (mg)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:26:50

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:43:22**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:05
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered empty.	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:26:50

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:43:22**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:05
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'as needed (PRN)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:26:50

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:43:22**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:05
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered empty.	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:26:50

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:43:22**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:05
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'Oral (ORAL)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:26:50

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:43:22

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:05
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered empty.	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:26:50

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:05
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '15 Feb 2021'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:26:50

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:43:22**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:05
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '0'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Feb 2021 16:26:50



**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:43:22**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:05
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:26:50

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:43:22**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:05
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '15 Feb 2021'	(b) (4) Carlton Griffin (b) (4) (b) (4)	22 Feb 2021 16:26:50

US3782100

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:43:22

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:05
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:26:50

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:43:22**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:05
User entered empty.	System	22 Feb 2021 16:26:50

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:05
User entered empty.	System	22 Feb 2021 16:26:50

**US3782100**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:43:22**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 12:05:05
User entered empty.	System	22 Feb 2021 16:26:50

**US3782100**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures Summary**

**Generated On: 10 Jun 2021 09:43:22**

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:06
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:45:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Dec 2020 17:23:04

US3782100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:43:22

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:50:35
User entered '2 Dec 2020'	(b) (4), (b) (6)	04 Dec 2020 17:23:51



US3782100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:43:22

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:50:37
User entered 'laparoscopic removal of abdominal adhesions'	(b) (4), (b) (6)	04 Dec 2020 17:23:51

**US3782100**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:50:39
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	04 Dec 2020 17:23:51

US3782100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:43:22

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:50:41
User entered empty.	(b) (4), (b) (6)	04 Dec 2020 17:23:51

US3782100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:43:22

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered '11 Feb 2021'	(b) (4) Carlton Griffin (b) (4)	22 Feb 2021 16:05:04

**US3782100**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'neck lift'	Carlton Griffin (b) (4)	22 Feb 2021 16:05:04

**US3782100**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'Other (OTHER)'	Carlton Griffin (b) (4)	22 Feb 2021 16:05:04

US3782100

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 10 Jun 2021 09:43:22

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 14:42:46
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:17:44
User entered 'elective cosmetic'	Carlton Griffin (b) (4)	22 Feb 2021 16:05:04

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered	System	05 Dec 2020 16:26:22
'USA-US125-2020-MRNA-1273-P301000012'		



**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'Yes (Y)'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'No (N)'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'No (N)'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'Yes (Y)'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'No (N)'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'No (N)'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'No (N)'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'Spyros'	System	05 Dec 2020 16:26:22



US3782100

Folder: SAE USA-US125-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'Kalams'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered '1161 21st Avenue South'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'Nashville'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered '37232'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 18:31:29
User entered 'US'	System	05 Dec 2020 16:26:52

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered '2'	System	08 Dec 2020 18:31:39
User entered '1'	System	05 Dec 2020 16:26:52

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'USA-US125-2020-MRNA-1273-P301000012'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'Yes (Y)'	System	05 Dec 2020 16:26:22



**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'No (N)'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'No (N)'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'Yes (Y)'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'No (N)'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'No (N)'	System	05 Dec 2020 16:26:22

US3782100

Folder: SAE USA-US125-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:22

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'No (N)'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'Spyros'	System	05 Dec 2020 16:26:22

US3782100

Folder: SAE USA-US125-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'Kalams'	System	05 Dec 2020 16:26:22



**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered '1161 21st Avenue South'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'Nashville'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered '37232'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 18:31:29
User entered 'US'	System	05 Dec 2020 16:26:52

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered '2'	System	08 Dec 2020 18:31:39
User entered '1'	System	05 Dec 2020 16:26:52

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:43:22**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered '05/Dec/2020 16:26'	System	05 Dec 2020 16:26:52

US3782100

Folder: SAE USA-US125-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:43:22

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 18:31:29
User entered 'I'	(b) (4), (b) (6)	05 Dec 2020 16:26:52

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'USA-US125-2020-MRNA-1273-P301000012'	System	05 Dec 2020 16:26:22



**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'Yes (Y)'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'No (N)'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'No (N)'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'Yes (Y)'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'No (N)'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'No (N)'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'No (N)'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'Spyros'	System	05 Dec 2020 16:26:22



US3782100

Folder: SAE USA-US125-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 10 Jun 2021 09:43:22

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'Kalams'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered '1161 21st Avenue South'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered 'Nashville'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Dec 2020 16:26:41
User entered '37232'	System	05 Dec 2020 16:26:22

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	08 Dec 2020 18:31:29
User entered 'US'	System	05 Dec 2020 16:26:52

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:43:22**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered '2'	System	08 Dec 2020 18:31:39
User entered '1'	System	05 Dec 2020 16:26:52

**US3782100**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000012**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:43:22**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered '08/Dec/2020 18:31'	System	08 Dec 2020 18:31:39

US3782100

Folder: SAE USA-US125-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:43:22

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 19:22:53
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:19:52
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	08 Dec 2020 18:31:39