

US3782153 (Prod: Vanderbilt University Medical Center)

Generated By: KC Joubran

Generated On: 10 Jun 2021 09:44:15

All time stamps listed in this document are displayed in GMT

US3782153

Form: Participant Creation

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

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[Participant ID](#)

US3782153

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

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US3782153

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	65
Age Units	YEARS
Age (Derived)	65
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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 26 Jan 2021 20:26:01

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Date of Informed Consent ( <i>dd MMM yyyy</i> )	04 SEP 2020
Month and Year of Informed Consent (derived)	SEP 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/> Amendment 2 <input type="radio"/> Amendment 3 <input checked="" type="radio"/> Amendment 4 <input type="radio"/> Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/> Inclusion/Exclusion <input type="radio"/> Cohort Full <input type="radio"/> Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 26 Jan 2021 20:26:01

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Were any significant conditions reported?

Yes ☒  
No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

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



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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Start Year (derived)	2016
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Condition	GENERALIZED CONTACT DERMATITIS
Start date (dd MMM yyyy)	24 AUG 2020
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)	24 AUG 2020
Stop date completely unknown	False
Start Month and Year (derived)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	AUG 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Condition	ALLERGIC RHINITIS
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Condition	ANXIETY
Start date (dd MMM yyyy)	UN APR 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	APR 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Condition	BILATERAL OOPHORECTOMY + HYSTERECTOMY
Start date (dd MMM yyyy)	UN APR 2008
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 APR 2008
Stop date completely unknown	False
Start Month and Year (derived)	APR 2008
Start Year (derived)	2008
Stop Month and Year (derived)	APR 2008
Stop Year (derived)	2008



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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment ( <i>dd MMM yyyy</i> )	04 SEP 2020
Time of assessment ( <i>00:00-23:59</i> )	14:15 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 14:15
Height ( <i>xxx.x</i> )	146.5 cm
Weight ( <i>xxx.x</i> )	52.8 kg
BMI ( <i>xxx.x</i> )	24.60133 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)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:26:01

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 SEP 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 26 Jan 2021 20:26:01

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Date of assessment (dd MMM yyyy) 04 SEP 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 APR 2008

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Jan 2021 20:26:01

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**Occupational Risk**

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**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)**

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**No Risk Identified** False

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 26 Jan 2021 20:26:01

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

What was the date of randomization? (dd MMM yyyy) 04 SEP 2020

What was the participant's randomization number? 190002

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Height	ND - Not Done
Weight	ND - Not Done



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

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)	04 SEP 2020
Time of assessment (00:00-23:59)	14:15 (24 HR)
Vital Signs Date and Time (derived)	04 SEP 2020 14:15
Temperature (xxx.x)	98.0 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)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

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)	4 SEP 2020
Time of assessment (00:00-23:59)	15:45 (24 HR)
Vital Signs Date and Time (derived)	4 SEP 2020 15:45
Temperature (xxx.x)	97.9 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	109 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

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) 04 SEP 2020

What was the treatment time? (00:00-23:59) 15:12 (24 HR)

Treatment Date and Time (derived) 04 SEP 2020 15:12

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 SEP 2020
Collection time (00:00-23:59)	14:35 (24 HR)
Collection date and time (derived)	04 SEP 2020 14:35

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Collection date (dd MMM yyyy)			04 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	14:40	04 SEP 2020 14:40
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 SEP 2020 15:46

PC Open Date & Time

04 SEP 2020 15:32

PC Close Date & Time

04 SEP 2020 18:02



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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**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 97.4 °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	04 SEP 2020 22:05
PC Open Date & Time	04 SEP 2020 18:57
PC Close Date & Time	05 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**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

97.9 °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

05 SEP 2020 20:17

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:44:15

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**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 23:32

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 23:01

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 SEP 2020 22:15

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:44:15

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**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

97.8 °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

09 SEP 2020 22:21

---

PC Open Date & Time

09 SEP 2020 12:00

---

PC Close Date & Time

10 SEP 2020 11:59

---

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**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

98.0 °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

10 SEP 2020 22:13

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 15:47

PC Open Date & Time

04 SEP 2020 15:32

PC Close Date & Time

04 SEP 2020 18:02



US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**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

04 SEP 2020 22:05

PC Open Date & Time

04 SEP 2020 18:57

PC Close Date & Time

05 SEP 2020 11:59

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

60

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

05 SEP 2020 20:15

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

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

60

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 SEP 2020 23:33

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**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

07 SEP 2020 23:04

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**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

08 SEP 2020 22:16

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:44:15

**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

09 SEP 2020 22:21

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**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

10 SEP 2020 22:13

PC Open Date & Time

10 SEP 2020 12:00

PC Close Date & Time

11 SEP 2020 11:59

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**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 ☐



US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 15:47
PC Open Date & Time	04 SEP 2020 15:32
PC Close Date & Time	04 SEP 2020 18:02

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**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 ☐

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

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

No ☒

Yes ☐

PC Time stamp	04 SEP 2020 22:06
PC Open Date & Time	04 SEP 2020 18:57
PC Close Date & Time	05 SEP 2020 11:59

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**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 ☒

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 20:18
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**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 ☒

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 23:33
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**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 ☒



US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 23:05
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

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

57 of 2293

EAB) (1725)

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

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

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

59 of 2293

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

Yes <input type="checkbox"/>	
PC Time stamp	09 SEP 2020 22:22
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

61 of 2293

EAB) (1725)

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

Yes <input type="checkbox"/>	
PC Time stamp	10 SEP 2020 22:14
PC Open Date & Time	10 SEP 2020 12:00
PC Close Date & Time	11 SEP 2020 11:59

US3782153

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3782153

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782153

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782153

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782153

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782153

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782153

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:26:02

Generated On: 10 Jun 2021 09:44:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 26 Jan 2021 20:26:02

Generated On: 10 Jun 2021 09:44:15

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)	6 OCT 2020
Time of assessment (00:00-23:59)	08:38 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 08:38
Temperature (xxx.x)	97.7 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 26 Jan 2021 20:26:02

Generated On: 10 Jun 2021 09:44:15

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)	6 OCT 2020
Time of assessment (00:00-23:59)	09:51 (24 HR)
Vital Signs Date and Time (derived)	6 OCT 2020 09:51
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
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)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	69 mmHg
Diastolic Blood Pressure units	MMHG



US3782153

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:26:02

Generated On: 10 Jun 2021 09:44:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 OCT 2020

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

US3782153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

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) 6 OCT 2020

What was the treatment time? (00:00-23:59) 09:19 (24 HR)

Treatment Date and Time (derived) 6 OCT 2020 09:19

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

US3782153

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:26:02

Generated On: 10 Jun 2021 09:44:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

6 OCT 2020

Collection time (00:00-23:59)

08:41 (24 HR)

Collection date and time (derived)

6 OCT 2020 08:41

US3782153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Collection date (dd MMM yyyy)			6 OCT 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	08:43	6 OCT 2020 08:43
Nasopharyngeal Swab 2	No		

US3782153

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 OCT 2020 09:52

PC Open Date & Time

06 OCT 2020 09:39

PC Close Date & Time

06 OCT 2020 12:09

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**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 97.2 °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	06 OCT 2020 22:39
PC Open Date & Time	06 OCT 2020 13:04
PC Close Date & Time	07 OCT 2020 11:59

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**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

97.4 °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

07 OCT 2020 22:24

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59



US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 OCT 2020 22:24

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °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

09 OCT 2020 21:58

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**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

10 OCT 2020 23:16

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:44:15

**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.

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

11 OCT 2020 22:10

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °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

13 OCT 2020 06:41

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**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

06 OCT 2020 09:53

PC Open Date & Time

06 OCT 2020 09:39

PC Close Date & Time

06 OCT 2020 12:09

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

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

60

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

06 OCT 2020 22:42

PC Open Date & Time

06 OCT 2020 13:04

PC Close Date & Time

07 OCT 2020 11:59

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**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

07 OCT 2020 22:25

PC Open Date & Time

07 OCT 2020 12:00

PC Close Date & Time

08 OCT 2020 11:59



US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**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

08 OCT 2020 22:25

PC Open Date & Time

08 OCT 2020 12:00

PC Close Date & Time

09 OCT 2020 11:59

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**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

09 OCT 2020 21:58

PC Open Date & Time

09 OCT 2020 12:00

PC Close Date & Time

10 OCT 2020 11:59

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**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

10 OCT 2020 23:17

PC Open Date & Time

10 OCT 2020 12:00

PC Close Date & Time

11 OCT 2020 11:59

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:44:15

**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

11 OCT 2020 22:10

PC Open Date & Time

11 OCT 2020 12:00

PC Close Date & Time

12 OCT 2020 11:59

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

13 OCT 2020 06:41

PC Open Date & Time

12 OCT 2020 12:00

PC Close Date & Time

13 OCT 2020 11:59

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**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 ☐

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

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

No ☒

Yes ☐

PC Time stamp	06 OCT 2020 09:54
PC Open Date & Time	06 OCT 2020 09:39
PC Close Date & Time	06 OCT 2020 12:09

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**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 ☐



US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

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

No ☒

Yes ☐

PC Time stamp	06 OCT 2020 22:42
PC Open Date & Time	06 OCT 2020 13:04
PC Close Date & Time	07 OCT 2020 11:59

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**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 ☒

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

Yes <input type="checkbox"/>	
PC Time stamp	07 OCT 2020 22:26
PC Open Date & Time	07 OCT 2020 12:00
PC Close Date & Time	08 OCT 2020 11:59

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**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 ☒

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

Yes <input type="checkbox"/>	
PC Time stamp	08 OCT 2020 22:26
PC Open Date & Time	08 OCT 2020 12:00
PC Close Date & Time	09 OCT 2020 11:59

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

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

101 of 2293

EAB) (1725)

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

Yes <input type="checkbox"/>	
PC Time stamp	09 OCT 2020 21:59
PC Open Date & Time	09 OCT 2020 12:00
PC Close Date & Time	10 OCT 2020 11:59

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

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)

103 of 2293



US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

Yes <input type="checkbox"/>	
PC Time stamp	10 OCT 2020 23:17
PC Open Date & Time	10 OCT 2020 12:00
PC Close Date & Time	11 OCT 2020 11:59

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

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 ☒

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

Yes <input type="checkbox"/>	
PC Time stamp	11 OCT 2020 22:10
PC Open Date & Time	11 OCT 2020 12:00
PC Close Date & Time	12 OCT 2020 11:59

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**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 ☒

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

Yes <input type="checkbox"/>	
PC Time stamp	13 OCT 2020 06:52
PC Open Date & Time	12 OCT 2020 12:00
PC Close Date & Time	13 OCT 2020 11:59

US3782153

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782153

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782153

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3782153

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782153

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782153

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782153

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:26:02

Generated On: 10 Jun 2021 09:44:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	3 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3782153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 26 Jan 2021 20:26:02

Generated On: 10 Jun 2021 09:44:15

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	3 NOV 2020
Time of assessment (00:00-23:59)	11:49 (24 HR)
Vital Signs Date and Time (derived)	3 NOV 2020 11:49
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)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	67 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3782153

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 26 Jan 2021 20:26:02

Generated On: 10 Jun 2021 09:44:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

3 NOV 2020

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

US3782153

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:26:02

Generated On: 10 Jun 2021 09:44:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

3 NOV 2020

Collection time (00:00-23:59)

11:51 (24 HR)

Collection date and time (derived)

3 NOV 2020 11:51

US3782153

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:26:02

Generated On: 10 Jun 2021 09:44:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



US3782153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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

07 NOV 2020 09:08:42

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3782153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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

13 NOV 2020 21:54:13

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3782153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

<b>TIMEPOINT</b>	DAY 82
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 13:56:37
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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 <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	29 NOV 2020 00:02:53
Patient Cloud Open Date & Time	29 NOV 2020 00:01
Patient Cloud Close Date & Time	03 DEC 2020 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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	06 DEC 2020 21:22:14
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 DEC 2020 08:39:38

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59



US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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

23 DEC 2020 09:18:31

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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

27 DEC 2020 08:07:56

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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

03 JAN 2021 00:22:33

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

<b>TIMEPOINT</b>	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 JAN 2021 10:50:14
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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

18 JAN 2021 16:05:03

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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

24 JAN 2021 15:46:53

Patient Cloud Open Date & Time

24 JAN 2021 00:01

Patient Cloud Close Date & Time

28 JAN 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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

02 FEB 2021 09:40:00

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 FEB 2021 19:47:51

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59



US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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

16 FEB 2021 10:37:04

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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

21 FEB 2021 00:05:10

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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

28 FEB 2021 00:02:01

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 20:17:52

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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

16 MAR 2021 09:28:28

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	21 MAR 2021 14:43:16
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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

30 MAR 2021 09:56:28

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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

04 APR 2021 01:09:27

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59



US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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

14 APR 2021 10:16:44

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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

18 APR 2021 00:06:39

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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

25 APR 2021 22:23:35

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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

03 MAY 2021 14:49:09

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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="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"/>

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

---

[Patient Cloud Close Date & Time](#)

---

13 MAY 2021 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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16 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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20 MAY 2021 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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23 MAY 2021 00:01

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[Patient Cloud Close Date & Time](#)

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27 MAY 2021 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 278

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

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

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

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

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

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

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

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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"/>

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

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[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 JUN 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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 <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"/>

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
<a href="#">Patient Cloud Open Date &amp; Time</a>	27 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 JUL 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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



US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	18 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 JUL 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

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

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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 JUL 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	29 JUL 2021 23:59
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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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"/>

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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"/>

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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08 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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12 AUG 2021 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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22 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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26 AUG 2021 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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29 AUG 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 SEP 2021 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

19 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

26 SEP 2021 00:01

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[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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°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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm 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>	03 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	07 OCT 2021 23:59



US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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"/>

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Close Date & Time](#)

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21 OCT 2021 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 418

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

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

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

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

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

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

[Patient Cloud Close Date & Time](#)

28 OCT 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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31 OCT 2021 00:01

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[Patient Cloud Close Date & Time](#)

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04 NOV 2021 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

14 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

18 NOV 2021 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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28 NOV 2021 00:01

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[Patient Cloud Close Date & Time](#)

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02 DEC 2021 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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>	05 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	09 DEC 2021 23:59
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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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°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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this 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>	26 DEC 2021 00:01
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<a href="#">Patient Cloud Close Date &amp; Time</a>	30 DEC 2021 23:59
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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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"/>

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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09 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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13 JAN 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 502

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

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

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

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

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

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

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

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

16 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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23 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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27 JAN 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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"/>

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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30 JAN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 FEB 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

13 FEB 2022 00:01

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[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Close Date & Time](#)

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24 FEB 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Close Date & Time](#)

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03 MAR 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

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

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[Patient Cloud Open Date & Time](#)

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06 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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10 MAR 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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13 MAR 2022 00:01

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17 MAR 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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20 MAR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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24 MAR 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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27 MAR 2022 00:01

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31 MAR 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

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

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[Patient Cloud Open Date & Time](#)

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03 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 APR 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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17 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 APR 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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24 APR 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 APR 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐  
Yes ☐

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

TIMEPOINT	DAY 614
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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15 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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19 MAY 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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22 MAY 2022 00:01

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[Patient Cloud Close Date & Time](#)

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26 MAY 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 642

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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"/>

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Close Date & Time](#)

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16 JUN 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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26 JUN 2022 00:01

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[Patient Cloud Close Date & Time](#)

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30 JUN 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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="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"/>

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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03 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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07 JUL 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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



US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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17 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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21 JUL 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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"/>

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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24 JUL 2022 00:01

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[Patient Cloud Close Date & Time](#)

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28 JUL 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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 <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"/>

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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11 AUG 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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14 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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18 AUG 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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21 AUG 2022 00:01

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[Patient Cloud Close Date & Time](#)

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25 AUG 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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"/>

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

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01 SEP 2022 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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04 SEP 2022 00:01

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08 SEP 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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11 SEP 2022 00:01

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15 SEP 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

DAY 747

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

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

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

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

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

Fever (Temperature  $\geq$  100.4°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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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18 SEP 2022 00:01

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22 SEP 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

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29 SEP 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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02 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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06 OCT 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Close Date & Time](#)

13 OCT 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

[Patient Cloud Close Date & Time](#)

20 OCT 2022 23:59

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**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 ☐

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Open Date & Time](#)

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30 OCT 2022 00:01

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[Patient Cloud Close Date & Time](#)

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03 NOV 2022 23:59

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US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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"/>

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

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[Patient Cloud Close Date & Time](#)

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10 NOV 2022 23:59

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US3782153

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary

Generated On: 10 Jun 2021 09:44:15

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 00:02:14

US3782153

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

1 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782153

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782153

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782153

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 26 Jan 2021 20:26:01

Generated On: 10 Jun 2021 09:44:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782153

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 19 Feb 2021 23:32:26

Generated On: 10 Jun 2021 09:44:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3782153

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 19 Feb 2021 23:32:26

Generated On: 10 Jun 2021 09:44:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782153

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 09 Apr 2021 01:20:49

Generated On: 10 Jun 2021 09:44:15

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3782153

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 01:20:49

Generated On: 10 Jun 2021 09:44:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3782153

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 09 Apr 2021 01:20:49

Generated On: 10 Jun 2021 09:44:15

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	6 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3782153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 09 Apr 2021 01:20:49

Generated On: 10 Jun 2021 09:44:15

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) \_\_\_\_\_

US3782153

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 09 Apr 2021 01:20:49

Generated On: 10 Jun 2021 09:44:15

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

6 APR 2021

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

US3782153

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 09 Apr 2021 01:20:49

Generated On: 10 Jun 2021 09:44:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	6 APR 2021
Collection time (00:00-23:59)	12:15 (24 HR)
Collection date and time (derived)	6 APR 2021 12:15

US3782153

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 09 Apr 2021 01:20:49

Generated On: 10 Jun 2021 09:44:15

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1



**US3782153**

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

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:44:15**

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*

**US3782153**

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

**Form: Continuing**

**Generated On: 10 Jun 2021 09:44:15**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3782153

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 10 Jun 2021 09:44:15

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"/>

**US3782153**

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

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

**Generated On: 10 Jun 2021 09:44:15**

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Generate Next COVID-19 Assessment

Yes ☐

No ☐

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US3782153

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

Form: Visit Date

Data signed: (b) (4) 26 Jan 2021 20:26:00

Generated On: 10 Jun 2021 09:44:15

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

Visit date (dd MMM yyyy)	14 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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US3782153

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

Form: Unblinding

Data signed: (b) (4) 09 Apr 2021 01:20:49

Generated On: 10 Jun 2021 09:44:15

Date of updated informed consent (dd MMM yyyy) 14 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 22 DEC 2020

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

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

US3782153

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 26 Jan 2021 20:26:00

Generated On: 10 Jun 2021 09:44:15

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

14 JAN 2021

Collection time (00:00-23:59)

13:18 (24 HR)

Collection date and time (derived)

14 JAN 2021 13:18

US3782153

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 26 Jan 2021 20:26:00

Generated On: 10 Jun 2021 09:44:15

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	14 JAN 2021
Collection time (00:00 - 23:59)	13:20
Collection Date and Time (derived)	14 JAN 2021 13:20



US3782153

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

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Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

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US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

AEID	USA-US125-2020-MRNA-1273-P30 1000009
Adverse event	APPENDICITIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	26 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)	27 NOV 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	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	True
Relationship to investigational product	Not Related <input 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	CHIEF COMPLAINT RT. ABD PAIN ON 26-NOV-2020, CT CONFIRMED APPENDICITIS, HAD APPENDECTOMY 27-NOV-2020
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
PRODUCTION RELEASE (v12.003 EAB) (1725)	

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**US3782153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Data signed:** (b) (4) 26 Jan 2021 20:25:59

**Generated On: 10 Jun 2021 09:44:15**

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Admitted to ICU Derived (CSA Programming Field Only)

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US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 26 Jan 2021 20:26:00

Generated On: 10 Jun 2021 09:44:15

---

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

Yes ☒

No ☐

---

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

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US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

Name of Medication AMLODOPINE

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	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 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

Name of Medication LOSARTAN

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN MAY 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

Name of Medication TOPROL XL

Prophylaxis Yes ☐  
No ☒

Indication HYPERTENSION

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2006	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Jan 2021 20:25:59

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Name of Medication BABY ASPIRIN

Prophylaxis Yes ☒  
No ☐

Indication CARDIOVASCULAR  
PROPHYLAXIS

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Jan 2021 20:25:59

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Jan 2021 20:25:59

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Name of Medication BUPROPION

Prophylaxis Yes ☐  
No ☒

Indication DEPRESSION

Dose per administration 450

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Jan 2021 20:25:59

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Name of Medication DECADRON

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED CONTACT  
DERMATITIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Jan 2021 20:25:59

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	Intraocular	<input type="radio"/>
	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)	24 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		24 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Jan 2021 20:25:59

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Name of Medication TRIAMCINOLONE

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED CONTACT  
DERMATITIS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Jan 2021 20:25:59

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	Intraocular	<input type="radio"/>
	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)	24 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		24 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Jan 2021 20:25:59

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Name of Medication PREDNISONE TAPER

Prophylaxis Yes ☐  
No ☒

Indication GENERALIZED CONTACT  
DERMATITIS

Dose per administration 60-20

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 60MG, 50MG, 40MG, 30MG,  
20MG, 20MG TAPERED ON  
CONSECUTIVE DAYS

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

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	Transdermal	<input type="checkbox"/>
	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)	24 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29 AUG 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

Name of Medication CETERIZINE

Prophylaxis Yes ☐  
No ☒

Indication ALLERGIC RHINITIS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	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 2009	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Jan 2021 20:25:59

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Name of Medication LORAZEPAM

Prophylaxis Yes ☐  
No ☒

Indication ANXIETY

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Jan 2021 20:25:59

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN APR 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Jan 2021 20:25:59

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Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐  
No ☒

Indication GERD

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 ☐  
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2006	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	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 SEP 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

Name of Medication RECLAST

Prophylaxis Yes ☐  
No ☒

Indication OSTEOPOROSIS

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	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)		18 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

Name of Medication HIGH DOSE INFLUENZA  
VACCINATION

Prophylaxis Yes ☒  
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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

If frequency is Other, specify

Route of administration Oral ☐  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	Intraocular	<input type="radio"/>
	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)	21 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		21 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

Name of Medication PROPOFOL

Prophylaxis Yes ☐  
No ☒

Indication APPENDICITIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	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)		27 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)		27 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☒  
No ☐

Indication APPENDICITIS

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	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)	27 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	27 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

Name of Medication MORPHINE SULFATE

Prophylaxis Yes ☐  
No ☒

Indication APPENDICITIS

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	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)	27 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) 27 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

Name of Medication OXYCODONE

Prophylaxis Yes ☐  
No ☒

Indication APPENDICITIS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	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)	27 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) 27 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

Name of Medication OXYCODONE

Prophylaxis Yes ☐  
No ☒

Indication APPENDICITIS (POST-OP PAIN)

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	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)	27 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication APPENDICITIS (POST-OP PAIN)

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	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)		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)		14 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

Name of Medication ZOFRAN

Prophylaxis Yes ☐  
No ☒

Indication APPENDICITIS

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	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)	27 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) 27 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"/>

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

Name of Medication PHENYLEPHRINE

Prophylaxis Yes ☐  
No ☒

Indication APPENDICITIS

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	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)		27 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)		27 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"/>

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

Name of Medication FENTANYL

Prophylaxis Yes ☐  
No ☒

Indication APPENDICITIS

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	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)	27 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)		27 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"/>

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

Name of Medication LIDOCAINE

Prophylaxis Yes ☐  
No ☒

Indication APPENDICITIS

Dose per administration 80

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	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)	27 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)	27 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"/>	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

Name of Medication ROCURONIUM

Prophylaxis Yes ☐  
No ☒

Indication APPENDICITIS

Dose per administration 70

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	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)	27 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)		27 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

Name of Medication SUGAMMADEX

Prophylaxis Yes ☐  
No ☒

Indication APPENDICITIS

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	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)	27 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)		27 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

Name of Medication PREVNAR23

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	Intraocular	<input type="radio"/>
	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)	4 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		4 JAN 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

Name of Medication TDAP VACCINE

Prophylaxis Yes ☒  
No ☐

Indication DIPHTHERIA, TETANUS,  
PERTUSSIS 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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Jan 2021 20:25:59

Generated On: 10 Jun 2021 09:44:15

	Intraocular	<input type="radio"/>
	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)	4 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		4 JAN 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"/>

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 26 Jan 2021 20:26:00

Generated On: 10 Jun 2021 09:44:15

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3782153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Jan 2021 20:26:00

Generated On: 10 Jun 2021 09:44:15

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
27 NOV 2020	APPENDECTOMY	Adverse Event	

US3782153

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 10 Jun 2021 09:44:15

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by  
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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



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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 10 Jun 2021 09:44:15

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 ☐

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 26 Jan 2021 20:26:00

Generated On: 10 Jun 2021 09:44:15

SAEID	USA-US125-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	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

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Jan 2021 20:26:00

Generated On: 10 Jun 2021 09:44:15

SAEID	USA-US125-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	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)	30/NOV/2020 16:39
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

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Jan 2021 20:26:00

Generated On: 10 Jun 2021 09:44:15

SAEID	USA-US125-2020-MRNA-1273-P301000009
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input type="radio"/> No <input checked="" type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input checked="" type="radio"/> No <input type="radio"/>
Investigator's First Name	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)	18/DEC/2020 09:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3782153 (Prod: Vanderbilt University Medical Center)

**US3782153**

**Form: Participant Creation**

**Generated On: 10 Jun 2021 09:44:15**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'US3782153'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:14:42

US3782153

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:44:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:36:07

**US3782153**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '04 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:14:43



US3782153

Folder: Screening

Form: Visit Date

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Clinic (Clinic)'	Amber Massey (b) (4)	04 Sep 2020 19:36:07

**US3782153**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:44:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered 'SCRN'	System	04 Sep 2020 19:36:07

US3782153

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:15

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered (b) (6) 1954'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:14:44

US3782153

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:15

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '65'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:36:23

**US3782153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:44:15**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered 'YEARS'	System	04 Sep 2020 19:36:23

**US3782153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:44:15**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered '65'	System	04 Sep 2020 19:37:21

**US3782153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:44:15**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Female (F)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:36:23

US3782153

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:15

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:36:23



US3782153

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:15

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'I'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:36:23

**US3782153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:44:15**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:36:23

US3782153

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:15

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	Amber Massey (b) (4)	04 Sep 2020 19:36:23

US3782153

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:15

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:36:23

**US3782153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:44:15**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:36:23

US3782153

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:15

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:36:23

US3782153

Folder: Screening

Form: Demographics

Generated On: 10 Jun 2021 09:44:15

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:36:23

**US3782153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:44:15**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:36:23



**US3782153**

**Folder: Screening**

**Form: Demographics**

**Generated On: 10 Jun 2021 09:44:15**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:36:23

US3782153

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:44:15

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '04 Sep 2020'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:37:21

US3782153

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered 'Sep 2020'	System	04 Sep 2020 19:37:21

US3782153

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered '2020'	System	04 Sep 2020 19:37:21

**US3782153**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:44:15**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Amendment 3 (3)'	Amber Massey (b) (4)	04 Sep 2020 19:37:21

US3782153

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:37:21

US3782153

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:44:15

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:37:21

US3782153

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:44:15

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:37:21



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Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:44:15

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:37:21

**US3782153**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 10 Jun 2021 09:44:15**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:14:43

US3782153

Folder: Screening

Form: Enrollment

Generated On: 10 Jun 2021 09:44:15

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered 'I'	System	04 Sep 2020 19:37:27

US3782153

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:37:27

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Folder: Screening

Form: Medical History Summary

Generated On: 10 Jun 2021 09:44:15

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:16:41

US3782153

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:44:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 21:01:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 21:01:50
Data point term sent to Coder	System	04 Sep 2020 21:00:59
User entered 'hypertension'	(b) (4), (b) (6)	04 Sep 2020 21:00:13

**US3782153**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'un UNK 2000'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:00:13

**US3782153**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:00:13



**US3782153**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:00:13

**US3782153**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:00:13

**US3782153**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:00:13

**US3782153**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered 'Jan 2000'	System	04 Sep 2020 21:00:13

**US3782153**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered '2000'	System	04 Sep 2020 21:00:13

US3782153

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered empty.	System	04 Sep 2020 21:00:13

US3782153

Folder: Screening

Form: Medical History (1)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered empty.	System	04 Sep 2020 21:00:13

US3782153

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:44:15

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 21:02:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 21:02:51
Data point term sent to Coder	System	04 Sep 2020 21:02:01
User entered 'depression'	(b) (4), (b) (6)	04 Sep 2020 21:01:08



**US3782153**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:01:08

**US3782153**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:01:08

**US3782153**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:44:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:01:08

**US3782153**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:01:08

**US3782153**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:44:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:01:08

**US3782153**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered 'Jan 2016'	System	04 Sep 2020 21:01:08

US3782153

Folder: Screening

Form: Medical History (2)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered '2016'	System	04 Sep 2020 21:01:08

**US3782153**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered empty.	System	04 Sep 2020 21:01:08



**US3782153**

**Folder: Screening**

**Form: Medical History (2)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered empty.	System	04 Sep 2020 21:01:08

US3782153

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:44:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis contact, LLT: Contact dermatitis - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 17:25:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 17:25:26
Data point term sent to Coder	System	28 Oct 2020 14:05:30
Coding entries removed.	Carlton Griffin (b) (4)	28 Oct 2020 14:05:01
User entered 'GENERALIZED CONTACT DERMATITIS' reason for change: Per Query Resolution	Carlton Griffin (b) (4)	28 Oct 2020 14:05:01
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Dermatitis contact, LLT: Contact dermatitis - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 21:02:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 21:02:51
Data point term sent to Coder	System	04 Sep 2020 21:02:01
User entered 'contact dermatitis'	(b) (4), (b) (6)	04 Sep 2020 21:01:44

**US3782153**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:01:44

**US3782153**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:01:44

**US3782153**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:44:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:03:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 21:01:44

US3782153

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '24 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:03:10
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 21:01:44

**US3782153**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:44:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:01:44

US3782153

Folder: Screening

Form: Medical History (3)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered 'Aug 2020'	System	04 Sep 2020 21:01:44



**US3782153**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered '2020'	System	04 Sep 2020 21:01:44

**US3782153**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered 'Aug 2020'	System	04 Sep 2020 21:03:10
User entered empty.	System	04 Sep 2020 21:01:44

**US3782153**

**Folder: Screening**

**Form: Medical History (3)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered '2020'	System	04 Sep 2020 21:03:10
User entered empty.	System	04 Sep 2020 21:01:44

US3782153

Folder: Screening

Form: Medical History (4)

Generated On: 10 Jun 2021 09:44:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Rhinitis allergic, LLT: Allergic rhinitis - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 21:04:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 21:04:43
Data point term sent to Coder	System	04 Sep 2020 21:04:06
User entered 'allergic rhinitis'	(b) (4), (b) (6)	04 Sep 2020 21:03:49

**US3782153**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'un UNK 2009'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:03:49

**US3782153**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:03:49

**US3782153**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:44:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:03:49

**US3782153**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:03:49



**US3782153**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:44:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:03:49

**US3782153**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered 'Jan 2009'	System	04 Sep 2020 21:03:49

**US3782153**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered '2009'	System	04 Sep 2020 21:03:49

**US3782153**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered empty.	System	04 Sep 2020 21:03:49

**US3782153**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered empty.	System	04 Sep 2020 21:03:49

US3782153

Folder: Screening

Form: Medical History (5)

Generated On: 10 Jun 2021 09:44:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 21:05:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 21:05:44
Data point term sent to Coder	System	04 Sep 2020 21:05:07
User entered 'anxiety'	(b) (4), (b) (6)	04 Sep 2020 21:04:13

**US3782153**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'un Apr 2017'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:04:13

**US3782153**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:04:13



**US3782153**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:44:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:04:13

**US3782153**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:04:13

**US3782153**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:44:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:04:13

**US3782153**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered 'Apr 2017'	System	04 Sep 2020 21:04:13

**US3782153**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered '2017'	System	04 Sep 2020 21:04:13

**US3782153**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered empty.	System	04 Sep 2020 21:04:13

**US3782153**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered empty.	System	04 Sep 2020 21:04:13

US3782153

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:44:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 21:05:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 21:05:44
Data point term sent to Coder	System	04 Sep 2020 21:05:07
User entered 'GERD'	(b) (4), (b) (6)	04 Sep 2020 21:04:46



**US3782153**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'un UNK 2006'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:04:46

**US3782153**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:04:46

**US3782153**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:44:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:04:46

**US3782153**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:04:46

**US3782153**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:44:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:04:46

US3782153

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered 'Jan 2006'	System	04 Sep 2020 21:04:46

US3782153

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered '2006'	System	04 Sep 2020 21:04:46

**US3782153**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered empty.	System	04 Sep 2020 21:04:46



US3782153

Folder: Screening

Form: Medical History (6)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered empty.	System	04 Sep 2020 21:04:46

US3782153

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:44:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
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.	(b) (4) Coder Import (b) (4) (b) (4)	04 Sep 2020 21:06:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Sep 2020 21:06:45
Data point term sent to Coder	System	04 Sep 2020 21:06:10
User entered 'hypercholesterolemia'	(b) (4), (b) (6)	04 Sep 2020 21:05:27

**US3782153**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'un Sep 2018'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:05:27

**US3782153**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:05:27

**US3782153**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:44:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:05:27

**US3782153**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:05:27

US3782153

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:44:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:05:27

US3782153

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered 'Sep 2018'	System	04 Sep 2020 21:05:27



**US3782153**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered '2018'	System	04 Sep 2020 21:05:27

US3782153

Folder: Screening

Form: Medical History (7)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered empty.	System	04 Sep 2020 21:05:27

**US3782153**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered empty.	System	04 Sep 2020 21:05:27

US3782153

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:44:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteoporosis, LLT: Osteoporosis - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 21:09:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Sep 2020 21:09:40
Data point term sent to Coder	System	04 Sep 2020 21:08:13
User entered 'osteoporosis'	(b) (4), (b) (6)	04 Sep 2020 21:07:40

**US3782153**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'un Jan 2018'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:07:40

US3782153

Folder: Screening

Form: Medical History (8)

Generated On: 10 Jun 2021 09:44:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:07:40

**US3782153**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:44:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:07:40

**US3782153**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:07:40



**US3782153**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:44:15**

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:07:40

**US3782153**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered 'Jan 2018'	System	04 Sep 2020 21:07:40

**US3782153**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered '2018'	System	04 Sep 2020 21:07:40

**US3782153**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered empty.	System	04 Sep 2020 21:07:40

**US3782153**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered empty.	System	04 Sep 2020 21:07:40

US3782153

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:44:15

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterosalpingo-oophorectomy, LLT: Ovariohysterectomy - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 08:19:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	08 Oct 2020 08:19:20
Data point term sent to Coder	System	05 Oct 2020 15:27:23
User entered 'BILATERAL OOPHORECTOMY + HYSTERECTOMY'	Carlton Griffin (b) (4)	05 Oct 2020 15:26:31

US3782153

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'UN Apr 2008'	Carlton Griffin (b) (4)	05 Oct 2020 15:26:31

US3782153

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:44:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	Carlton Griffin (b) (4)	05 Oct 2020 15:26:31



**US3782153**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:44:15**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	Carlton Griffin (b) (4)	05 Oct 2020 15:26:31

**US3782153**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'UN Apr 2008'	(b) (4) Carlton Griffin (b) (4)	05 Oct 2020 15:26:31

US3782153

Folder: Screening

Form: Medical History (9)

Generated On: 10 Jun 2021 09:44:15

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	Carlton Griffin (b) (4)	05 Oct 2020 15:26:31

**US3782153**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered 'Apr 2008'	System	05 Oct 2020 15:26:31

**US3782153**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered '2008'	System	05 Oct 2020 15:26:31

**US3782153**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered 'Apr 2008'	System	05 Oct 2020 15:26:31

**US3782153**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered '2008'	System	05 Oct 2020 15:26:31

US3782153

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:16:34



US3782153

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '04 Sep 2020'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:16:34

US3782153

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '14:15'	Amber Massey (b) (4)	04 Sep 2020 20:16:34

**US3782153**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:44:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered '04 Sep 2020 14:15'	System	04 Sep 2020 20:16:34

US3782153

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '146.5' cm	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:16:34
DataPoint set to visible.	(b) (4) System	04 Sep 2020 19:37:27

US3782153

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '52.8' kg	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:16:34
DataPoint set to visible.	(b) (4) System	04 Sep 2020 19:37:27

**US3782153**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:44:15**

[BMI \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered '24.60133'	System	04 Sep 2020 20:16:34
DataPoint set to visible.	System	04 Sep 2020 19:37:27

**US3782153**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:44:15**

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered 'kg/m2'	System	04 Sep 2020 20:16:34
DataPoint set to visible.	System	04 Sep 2020 19:37:27

US3782153

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered missing code ND - Not Done.	Amber Massey (b) (4)	04 Sep 2020 20:16:34



US3782153

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Oral (Oral)'	Amber Massey (b) (4)	04 Sep 2020 20:16:34

US3782153

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:16:34

US3782153

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:16:34

**US3782153**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:44:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered 'bpm'	System	04 Sep 2020 20:16:34

US3782153

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:16:34

US3782153

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered 'breaths/min'	System	04 Sep 2020 20:16:34

US3782153

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:16:34

**US3782153**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:44:15**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered 'mmHg'	System	04 Sep 2020 20:16:34



US3782153

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered missing code ND - Not Done.	Amber Massey (b) (4)	04 Sep 2020 20:16:34

US3782153

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User entered 'mmHg'	System	04 Sep 2020 20:16:34

US3782153

Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29

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Folder: Screening

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29

US3782153

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:44:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:37:41

US3782153

Folder: Screening

Form: Physical Examination

Generated On: 10 Jun 2021 09:44:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '04 Sep 2020'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:37:41

US3782153

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:44:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '04 Sep 2020'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:18:26

US3782153

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:44:15

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:18:26



US3782153

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:44:15

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User closed query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:13:50
Query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' answered with 'MH ecrf updated' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	05 Oct 2020 15:24:58
User opened query 'Per DM CLR: Note,If No, what is the reason?= Surgically sterile; however no corresponding procedure is recorded in MH ecrf. Please update MH ecrf to include the procedure and the medical condition associated with the procedure if applicable. Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Oct 2020 07:57:38
User entered 'Surgically sterile (SURGICALLY STERILE)'	Amber Massey (b) (4) (b) (4)	04 Sep 2020 20:18:26

US3782153

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:44:15

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:18:26

US3782153

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:44:15

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'un Apr 2008'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:18:26

US3782153

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:44:15

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	Amber Massey (b) (4)	04 Sep 2020 20:18:26

US3782153

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:18:26

US3782153

Folder: Screening

Form: Childbearing Potential

Generated On: 10 Jun 2021 09:44:15

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	Amber Massey (b) (4)	04 Sep 2020 20:18:26

US3782153

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:15

**Healthcare workers** (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:18:02

US3782153

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:15

**Emergency Response** (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:18:02



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Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:15

**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)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	04 Sep 2020 20:18:02

US3782153

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:15

**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)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	Amber Massey (b) (4)	04 Sep 2020 20:18:02

US3782153

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:15

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:18:02

US3782153

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:15

[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)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	Amber Massey (b) (4)	04 Sep 2020 20:18:02

US3782153

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:15

**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)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	Amber Massey (b) (4)	04 Sep 2020 20:18:02

US3782153

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:15

**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)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:18:02

US3782153

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:15

[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)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:18:02

US3782153

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:15

**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)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	Amber Massey (b) (4)	04 Sep 2020 20:18:02



US3782153

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:15

**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)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	Amber Massey (b) (4)	04 Sep 2020 20:18:02

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Folder: Screening

Form: Risk of Exposure

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:18:02

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:18:02

US3782153

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:15

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:18:02

US3782153

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:15

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	Amber Massey (b) (4)	04 Sep 2020 20:18:02

US3782153

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:15

**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)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	Amber Massey (b) (4)	04 Sep 2020 20:18:02

US3782153

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:15

[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)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:18:02

US3782153

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:15

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)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	Amber Massey (b) (4)	04 Sep 2020 20:18:02



US3782153

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:15

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'I'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:18:02

US3782153

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:15

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:18:02

US3782153

Folder: Screening

Form: Risk of Exposure

Generated On: 10 Jun 2021 09:44:15

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:47:29
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:18:02

US3782153

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:44:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:37:53

US3782153

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '04 Sep 2020'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 19:37:53

US3782153

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 10 Jun 2021 09:44:15

[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 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Clinic (Clinic)'	(b) (4) Amber Massey (b) (4) (b) (4)	04 Sep 2020 19:37:53

**US3782153**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:44:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'VISIT1'	System	04 Sep 2020 19:37:53

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '04 SEP 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:49:18



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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:44:15

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '190002'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:49:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:44:15

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Sep 2020 19:49:18

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:44:15

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 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	04 Sep 2020 20:18:40

US3782153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:44:15

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 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User closed query 'Per CDM: Please note Significant cardiac disease is recorded as "Yes", however it has not been entered in Medical History Pages. Please review and update accordingly.	(b) (4) (b) (4), (b) (6)	21 Dec 2020 12:17:23
' (Site from DM). Query 'Per CDM: Please note Significant cardiac disease is recorded as "Yes", however it has not been entered in Medical History Pages. Please review and update accordingly.	Carlton Griffin (b) (4) (b) (4)	17 Dec 2020 13:58:08
' answered with 'entry error in medidata. did not randomize participant into the risk category. ' (Site from DM). User entered 'No (N)' reason for change: Data Entry Error	Carlton Griffin (b) (4) (b) (4)	17 Dec 2020 13:57:35
User opened query 'Per CDM: Please note Significant cardiac disease is recorded as "Yes", however it has not been entered in Medical History Pages. Please review and update accordingly.	(b) (4), (b) (6)	15 Dec 2020 20:15:45
' (Site from DM). User entered 'Yes (Y)'	Amber Massey (b) (4) (b) (4)	04 Sep 2020 20:18:40

US3782153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:44:15

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) Amber Massey (b) (4) (b) (4)	04 Sep 2020 20:18:40

US3782153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:44:15

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:18:40

US3782153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:44:15

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:18:40

US3782153

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 10 Jun 2021 09:44:15

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Sep 2020 17:44:11
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 05:29:07
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 05:29:06



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:44:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:19:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:44:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:19:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:44:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:19:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:44:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:19:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User accepted default value 'Pre-Dose (PREDOSE)'	Amber Massey (b) (4)	04 Sep 2020 20:19:31
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4) (b) (4)	04 Sep 2020 20:19:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '04 Sep 2020'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:19:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '14:15'	(b) (4) Amber Massey (b) (4) (b) (4)	04 Sep 2020 20:19:31



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered '04 Sep 2020 14:15'	System	04 Sep 2020 20:19:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '98.0' F	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:19:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Oral (Oral)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:19:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) Amber Massey (b) (4) (b) (4)	04 Sep 2020 20:19:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '66'	(b) (4) Amber Massey (b) (4) (b) (4)	04 Sep 2020 20:19:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'bpm'	System	04 Sep 2020 20:19:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '16'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:19:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'breaths/min'	System	04 Sep 2020 20:19:31



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '125'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:19:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'mmHg'	System	04 Sep 2020 20:19:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '70'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:19:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'mmHg'	System	04 Sep 2020 20:19:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:44:15

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:19:31

US3782153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 10 Jun 2021 09:44:15

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered missing code ND - Not Done.	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:19:31

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	04 Sep 2020 20:53:18

US3782153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:53:18



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '4 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:53:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '15:45'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:53:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered '4 Sep 2020 15:45'	System	04 Sep 2020 20:53:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '97.9' F	(b) (4), (b) (6)	04 Sep 2020 20:53:18

US3782153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:53:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:53:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '61'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:53:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'bpm'	System	04 Sep 2020 20:53:18



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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

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[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '16'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:53:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'breaths/min'	System	04 Sep 2020 20:53:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '109'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:53:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'mmHg'	System	04 Sep 2020 20:53:18

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '65'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 20:53:18

US3782153

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'mmHg'	System	04 Sep 2020 20:53:18

US3782153

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:44:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:20:05

US3782153

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 10 Jun 2021 09:44:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:20:05



US3782153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:44:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:21:04

US3782153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:44:15

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:21:04

US3782153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:44:15

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 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:21:04

US3782153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:44:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'MRNA-1273 OR PLACEBO'	System	04 Sep 2020 20:21:04

US3782153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:44:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '04 Sep 2020'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:21:04

US3782153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:44:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '15:12'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:21:04

US3782153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:44:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered '04 Sep 2020 15:12'	System	04 Sep 2020 20:21:04

US3782153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:44:15

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Left Arm (LEFT ARM)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:21:04



US3782153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:44:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'ONCE'	System	04 Sep 2020 20:21:04

US3782153

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 10 Jun 2021 09:44:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'INTRAMUSCULAR'	System	04 Sep 2020 20:21:04

US3782153

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:21:31

US3782153

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '04 Sep 2020'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:21:31

US3782153

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '14:35'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:21:31

US3782153

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:15

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered '04 Sep 2020 14:35'	System	04 Sep 2020 20:21:31

US3782153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:44:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '04 Sep 2020'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:21:44

US3782153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:44:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Amber Massey (b) (4)	04 Sep 2020 20:21:44



US3782153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:44:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:21:44

US3782153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:44:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '14:40'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:21:44

US3782153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:44:15

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered '04 Sep 2020 14:40'	System	04 Sep 2020 20:21:44

US3782153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:44:15

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Amber Massey (b) (4)	04 Sep 2020 20:21:44

US3782153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:44:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:21:44

US3782153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:44:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:21:44

US3782153

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:44:15

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered empty.	System	04 Sep 2020 20:21:44

US3782153

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 10 Jun 2021 09:44:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Amber Massey (b) (4)	04 Sep 2020 20:21:49



**US3782153**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:44:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'I'	System	04 Sep 2020 20:21:49

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T15:45:29', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '9dac6088-29f7-45b8-9a2c-6274d9c91156' User entered 'Yes (Y)'	System	04 Sep 2020 20:46:37
	System	04 Sep 2020 20:46:37

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T15:45:38', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '9dac6088-29f7-45b8-9a2c-6274d9c91156' User entered '97.9'	System	04 Sep 2020 20:46:37
	System	04 Sep 2020 20:46:37

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T15:45:43', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '9dac6088-29f7-45b8-9a2c-6274d9c91156'	System	04 Sep 2020 20:46:37
User entered 'No (N)'	System	04 Sep 2020 20:46:37

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T15:46:33', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '9dac6088-29f7-45b8-9a2c-6274d9c91156' User entered '04 Sep 2020 15:46'	System	04 Sep 2020 20:46:37
	System	04 Sep 2020 20:46:37

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '04 Sep 2020 15:32'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '04 Sep 2020 18:02'	System	04 Sep 2020 20:21:04



US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T22:04:36', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '9ae82960-0c69-4fe0-9248-45b8dcffa98d' User entered 'Yes (Y)'	System	05 Sep 2020 03:06:07
	System	05 Sep 2020 03:06:07

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T22:04:46', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '9ae82960-0c69-4fe0-9248-45b8dcffa98d' User entered '97.4'	System	05 Sep 2020 03:06:07
	System	05 Sep 2020 03:06:07

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T22:04:49', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '9ae82960-0c69-4fe0-9248-45b8dcffa98d' User entered 'No (N)'	System	05 Sep 2020 03:06:07
	System	05 Sep 2020 03:06:07

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T22:05:16', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '9ae82960-0c69-4fe0-9248-45b8dcffa98d' User entered '04 Sep 2020 22:05'	System	05 Sep 2020 03:06:07
	System	05 Sep 2020 03:06:07

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '04 Sep 2020 18:57'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 2'	System	04 Sep 2020 20:21:04



US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:44:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-05T20:17:21', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '85a8ddb0-1ac4-4fba-906d-14fdc6ca0ccd' User entered 'Yes (Y)'	System	06 Sep 2020 01:17:53
	System	06 Sep 2020 01:17:53

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:44:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-05T20:17:37', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '85a8ddb0-1ac4-4fba-906d-14fdc6ca0ccd' User entered '97.9'	System	06 Sep 2020 01:17:53
	System	06 Sep 2020 01:17:53

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-05T20:17:41', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '85a8ddb0-1ac4-4fba-906d-14fdc6ca0ccd' User entered 'No (N)'	System	06 Sep 2020 01:17:53
	System	06 Sep 2020 01:17:53

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:44:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-05T20:17:49', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '85a8ddb0-1ac4-4fba-906d-14fdc6ca0ccd' User entered '05 Sep 2020 20:17'	System	06 Sep 2020 01:17:53
	System	06 Sep 2020 01:17:53

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 3'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:44:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-06T23:31:58', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '87b20b5d-27f5-4c0d-adec-0e44de4eaf3f' User entered 'Yes (Y)'	System	07 Sep 2020 04:32:52
	System	07 Sep 2020 04:32:52



US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:44:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-06T23:32:05', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '87b20b5d-27f5-4c0d-adec-0e44de4eaf3f' User entered '97.2'	System	07 Sep 2020 04:32:52
	System	07 Sep 2020 04:32:52

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-06T23:32:09', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '87b20b5d-27f5-4c0d-adec-0e44de4eaf3f' User entered 'No (N)'	System	07 Sep 2020 04:32:52
	System	07 Sep 2020 04:32:52

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:44:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-06T23:32:17', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '87b20b5d-27f5-4c0d-adec-0e44de4eaf3f' User entered '06 Sep 2020 23:32'	System	07 Sep 2020 04:32:52
	System	07 Sep 2020 04:32:52

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 4'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:44:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-07T22:57:36', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'fbe928e9-e05f-47b2-8278-87815ef74e01' User entered 'Yes (Y)'	System	08 Sep 2020 04:01:39
	System	08 Sep 2020 04:01:39

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:44:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-07T23:01:22', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'fbe928e9-e05f-47b2-8278-87815ef74e01' User entered '97.0'	System	08 Sep 2020 04:01:39
	System	08 Sep 2020 04:01:39



US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-07T23:01:25', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'fbe928e9-e05f-47b2-8278-87815ef74e01'	System	08 Sep 2020 04:01:39
User entered 'No (N)'	System	08 Sep 2020 04:01:39

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:44:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-07T23:01:33', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'fbe928e9-e05f-47b2-8278-87815ef74e01' User entered '07 Sep 2020 23:01'	System	08 Sep 2020 04:01:39
	System	08 Sep 2020 04:01:39

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 5'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:44:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-08T22:15:14', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '5bd25d2d-c5ff-45fb-8c42-0f77e5b9e253' User entered 'Yes (Y)'	System	09 Sep 2020 03:15:37
	System	09 Sep 2020 03:15:37

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:44:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-08T22:15:24', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '5bd25d2d-c5ff-45fb-8c42-0f77e5b9e253' User entered '96.8'	System	09 Sep 2020 03:15:37
	System	09 Sep 2020 03:15:37

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-08T22:15:28', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '5bd25d2d-c5ff-45fb-8c42-0f77e5b9e253'	System	09 Sep 2020 03:15:37
User entered 'No (N)'	System	09 Sep 2020 03:15:37



**US3782153**

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

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

**Generated On: 10 Jun 2021 09:44:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-08T22:15:34', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '5bd25d2d-c5ff-45fb-8c42-0f77e5b9e253'	System	09 Sep 2020 03:15:37
User entered '08 Sep 2020 22:15'	System	09 Sep 2020 03:15:37

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 6'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:44:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-09T22:20:56', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '238c58a6-2c4f-4183-8d62-bae2404f970d' User entered 'Yes (Y)'	System	10 Sep 2020 03:21:21
	System	10 Sep 2020 03:21:21

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:44:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-09T22:21:07', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '238c58a6-2c4f-4183-8d62-bae2404f970d' User entered '97.8'	System	10 Sep 2020 03:21:21
	System	10 Sep 2020 03:21:21

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-09T22:21:10', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '238c58a6-2c4f-4183-8d62-bae2404f970d' User entered 'No (N)'	System	10 Sep 2020 03:21:21
	System	10 Sep 2020 03:21:21

**US3782153**

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

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

**Generated On: 10 Jun 2021 09:44:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-09T22:21:18', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '238c58a6-2c4f-4183-8d62-bae2404f970d' User entered '09 Sep 2020 22:21'	System	10 Sep 2020 03:21:21
	System	10 Sep 2020 03:21:21



US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 7'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:44:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-10T22:12:42', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'e4e07c7c-ac39-49a7-9022-320d4bc4bcff' User entered 'Yes (Y)'	System	11 Sep 2020 03:13:33
	System	11 Sep 2020 03:13:33

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:44:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-10T22:13:15', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'e4e07c7c-ac39-49a7-9022-320d4bc4bcff' User entered '98.0'	System	11 Sep 2020 03:13:33
	System	11 Sep 2020 03:13:33

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-10T22:13:21', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'e4e07c7c-ac39-49a7-9022-320d4bc4bcff'	System	11 Sep 2020 03:13:33
User entered 'No (N)'	System	11 Sep 2020 03:13:33

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:44:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-10T22:13:28', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'e4e07c7c-ac39-49a7-9022-320d4bc4bcff' User entered '10 Sep 2020 22:13'	System	11 Sep 2020 03:13:33
	System	11 Sep 2020 03:13:33

US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:21:04



US3782153

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T15:46:47', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'bd925a7d-7af2-4cdc-9f70-12dde5523510' User entered 'None (1)'	System	04 Sep 2020 20:47:16
	System	04 Sep 2020 20:47:16

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T15:46:51', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'bd925a7d-7af2-4cdc-9f70-12dde5523510' User entered 'No (N)'	System	04 Sep 2020 20:47:16
	System	04 Sep 2020 20:47:16

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T15:46:55', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'bd925a7d-7af2-4cdc-9f70-12dde5523510' User entered 'No (N)'	System	04 Sep 2020 20:47:16
	System	04 Sep 2020 20:47:16

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T15:47:02', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'bd925a7d-7af2-4cdc-9f70-12dde5523510' User entered 'None (1)'	System	04 Sep 2020 20:47:16
	System	04 Sep 2020 20:47:16

**US3782153**

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

**Form: Injection Site\_Day(1/1)**

**Generated On: 10 Jun 2021 09:44:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T15:47:14', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'bd925a7d-7af2-4cdc-9f70-12dde5523510' User entered '04 Sep 2020 15:47'	System	04 Sep 2020 20:47:16
	System	04 Sep 2020 20:47:16

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '04 Sep 2020 15:32'	System	04 Sep 2020 20:21:04



US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '04 Sep 2020 18:02'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T22:05:28', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0cd04c82-20c4-4dd2-ac1c-176ed748044e' User entered 'None (1)'	System	05 Sep 2020 03:06:18
	System	05 Sep 2020 03:06:18

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T22:05:31', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0cd04c82-20c4-4dd2-ac1c-176ed748044e' User entered 'No (N)'	System	05 Sep 2020 03:06:18
	System	05 Sep 2020 03:06:18

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T22:05:35', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0cd04c82-20c4-4dd2-ac1c-176ed748044e' User entered 'No (N)'	System	05 Sep 2020 03:06:18
	System	05 Sep 2020 03:06:18

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T22:05:44', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0cd04c82-20c4-4dd2-ac1c-176ed748044e' User entered 'None (1)'	System	05 Sep 2020 03:06:18
	System	05 Sep 2020 03:06:18

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T22:05:56', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0cd04c82-20c4-4dd2-ac1c-176ed748044e' User entered '04 Sep 2020 22:05'	System	05 Sep 2020 03:06:18
	System	05 Sep 2020 03:06:18

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '04 Sep 2020 18:57'	System	04 Sep 2020 20:21:04



US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 2'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-05T20:08:26', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '6fd9bbb1-9426-4876-89ba-c8dbebe4b4b1'	System	06 Sep 2020 01:15:57
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 01:15:57

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:44:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-05T20:08:32', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '6fd9bbb1-9426-4876-89ba-c8dbebe4b4b1' User entered 'No (N)'	System	06 Sep 2020 01:15:57
	System	06 Sep 2020 01:15:57

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-05T20:08:42', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '6fd9bbb1-9426-4876-89ba-c8dbebe4b4b1' User entered 'Yes (Y)'	System	06 Sep 2020 01:15:57
	System	06 Sep 2020 01:15:57

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:44:15

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-05T20:14:29', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '6fd9bbb1-9426-4876-89ba-c8dbebe4b4b1' User entered '60'	System	06 Sep 2020 01:15:57
	System	06 Sep 2020 01:15:57

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-05T20:12:12', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '6fd9bbb1-9426-4876-89ba-c8dbebe4b4b1' User entered 'None (1)'	System	06 Sep 2020 01:15:57
	System	06 Sep 2020 01:15:57

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:44:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-05T20:15:55', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '6fd9bbb1-9426-4876-89ba-c8dbebe4b4b1' User entered '05 Sep 2020 20:15'	System	06 Sep 2020 01:15:57
	System	06 Sep 2020 01:15:57



US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 3'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-06T23:32:25', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'c11f7871-4faf-4798-8a57-269477596bf5'	System	07 Sep 2020 04:34:57
User entered 'Does not interfere with activity (2)'	System	07 Sep 2020 04:34:57

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:44:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-06T23:32:28', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'c11f7871-4faf-4798-8a57-269477596bf5' User entered 'No (N)'	System	07 Sep 2020 04:34:57
	System	07 Sep 2020 04:34:57

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-06T23:32:33', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'c11f7871-4faf-4798-8a57-269477596bf5'	System	07 Sep 2020 04:34:57
User entered 'Yes (Y)'	System	07 Sep 2020 04:34:57

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:44:15

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-06T23:32:43', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'c11f7871-4faf-4798-8a57-269477596bf5' User entered '60'	System	07 Sep 2020 04:34:57
	System	07 Sep 2020 04:34:57

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-06T23:33:07', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'c11f7871-4faf-4798-8a57-269477596bf5'	System	07 Sep 2020 04:34:57
User entered 'None (1)'	System	07 Sep 2020 04:34:57



**US3782153**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:44:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-06T23:33:20', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'c11f7871-4faf-4798-8a57-269477596bf5' User entered '06 Sep 2020 23:33'	System	07 Sep 2020 04:34:57
	System	07 Sep 2020 04:34:57

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 4'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-07T23:01:51', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '14fe1afa-c419-4c27-b2a6-28d7d6ca45b9'	System	08 Sep 2020 04:04:29
User entered 'None (1)'	System	08 Sep 2020 04:04:29

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:44:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-07T23:01:54', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '14fe1afa-c419-4c27-b2a6-28d7d6ca45b9' User entered 'No (N)'	System	08 Sep 2020 04:04:29
	System	08 Sep 2020 04:04:29

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-07T23:04:03', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '14fe1afa-c419-4c27-b2a6-28d7d6ca45b9' User entered 'No (N)'	System	08 Sep 2020 04:04:29
	System	08 Sep 2020 04:04:29

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-07T23:04:17', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '14fe1afa-c419-4c27-b2a6-28d7d6ca45b9'	System	08 Sep 2020 04:04:29
User entered 'None (1)'	System	08 Sep 2020 04:04:29



US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:44:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-07T23:04:27', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '14fe1afa-c419-4c27-b2a6-28d7d6ca45b9' User entered '07 Sep 2020 23:04'	System	08 Sep 2020 04:04:29
	System	08 Sep 2020 04:04:29

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 5'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-08T22:15:43', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'f009cb4a-441e-460a-9bc5-adf1c08b26fd' User entered 'None (1)'	System	09 Sep 2020 03:16:06
	System	09 Sep 2020 03:16:06

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:44:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-08T22:15:46', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'f009cb4a-441e-460a-9bc5-adf1c08b26fd' User entered 'No (N)'	System	09 Sep 2020 03:16:06
	System	09 Sep 2020 03:16:06

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-08T22:15:49', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'f009cb4a-441e-460a-9bc5-adf1c08b26fd' User entered 'No (N)'	System	09 Sep 2020 03:16:06
	System	09 Sep 2020 03:16:06

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-08T22:15:56', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'f009cb4a-441e-460a-9bc5-adf1c08b26fd' User entered 'None (1)'	System	09 Sep 2020 03:16:06
	System	09 Sep 2020 03:16:06



US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:44:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-08T22:16:03', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'f009cb4a-441e-460a-9bc5-adf1c08b26fd' User entered '08 Sep 2020 22:16'	System	09 Sep 2020 03:16:06
	System	09 Sep 2020 03:16:06

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 6'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-09T22:21:23', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '1535e142-780f-4664-a5b4-2a2f55a3ce27'	System	10 Sep 2020 03:21:36
User entered 'None (1)'	System	10 Sep 2020 03:21:36

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:44:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-09T22:21:26', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '1535e142-780f-4664-a5b4-2a2f55a3ce27' User entered 'No (N)'	System	10 Sep 2020 03:21:36
	System	10 Sep 2020 03:21:36

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-09T22:21:28', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '1535e142-780f-4664-a5b4-2a2f55a3ce27' User entered 'No (N)'	System	10 Sep 2020 03:21:36
	System	10 Sep 2020 03:21:36

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-09T22:21:30', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '1535e142-780f-4664-a5b4-2a2f55a3ce27'	System	10 Sep 2020 03:21:36
User entered 'None (1)'	System	10 Sep 2020 03:21:36



US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:44:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-09T22:21:34', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '1535e142-780f-4664-a5b4-2a2f55a3ce27' User entered '09 Sep 2020 22:21'	System	10 Sep 2020 03:21:36
	System	10 Sep 2020 03:21:36

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 7'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-10T22:13:36', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4f1e39e2-552a-4c4e-8452-74201ff5faad'	System	11 Sep 2020 03:13:55
User entered 'None (1)'	System	11 Sep 2020 03:13:55

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:44:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-10T22:13:39', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4f1e39e2-552a-4c4e-8452-74201ff5faad'	System	11 Sep 2020 03:13:55
User entered 'No (N)'	System	11 Sep 2020 03:13:55

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-10T22:13:42', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4f1e39e2-552a-4c4e-8452-74201ff5faad' User entered 'No (N)'	System	11 Sep 2020 03:13:55
	System	11 Sep 2020 03:13:55

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-10T22:13:45', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4f1e39e2-552a-4c4e-8452-74201ff5faad' User entered 'None (1)'	System	11 Sep 2020 03:13:55
	System	11 Sep 2020 03:13:55



US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:44:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-10T22:13:49', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4f1e39e2-552a-4c4e-8452-74201ff5faad' User entered '10 Sep 2020 22:13'	System	11 Sep 2020 03:13:55
	System	11 Sep 2020 03:13:55

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T15:47:34', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4da8496d-5a91-41a5-b9f2-dff8ad1737ae' User entered 'None (0)'	System	04 Sep 2020 20:47:57
	System	04 Sep 2020 20:47:57

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T15:47:38', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4da8496d-5a91-41a5-b9f2-dff8ad1737ae' User entered 'None (0)'	System	04 Sep 2020 20:47:57
	System	04 Sep 2020 20:47:57

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T15:47:40', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4da8496d-5a91-41a5-b9f2-dff8ad1737ae' User entered 'None (0)'	System	04 Sep 2020 20:47:57
	System	04 Sep 2020 20:47:57

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T15:47:42', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4da8496d-5a91-41a5-b9f2-dff8ad1737ae' User entered 'None (0)'	System	04 Sep 2020 20:47:57
	System	04 Sep 2020 20:47:57



US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T15:47:45', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4da8496d-5a91-41a5-b9f2-dff8ad1737ae' User entered 'None (0)'	System	04 Sep 2020 20:47:57
	System	04 Sep 2020 20:47:57

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T15:47:47', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4da8496d-5a91-41a5-b9f2-dff8ad1737ae' User entered 'None (0)'	System	04 Sep 2020 20:47:57
	System	04 Sep 2020 20:47:57

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T15:47:50', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4da8496d-5a91-41a5-b9f2-dff8ad1737ae' User entered 'No (N)'	System	04 Sep 2020 20:47:57
	System	04 Sep 2020 20:47:57

**US3782153**

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

**Form: General\_Day(1/1)**

**Generated On: 10 Jun 2021 09:44:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T15:47:54', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4da8496d-5a91-41a5-b9f2-dff8ad1737ae' User entered '04 Sep 2020 15:47'	System	04 Sep 2020 20:47:57
	System	04 Sep 2020 20:47:57

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '04 Sep 2020 15:32'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '04 Sep 2020 18:02'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 1, after vaccination (at home)'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T22:06:08', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4d0edd84-cb05-4306-b6f2-250e09cbd744' User entered 'None (0)'	System	05 Sep 2020 03:06:43
	System	05 Sep 2020 03:06:43



US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T22:06:12', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4d0edd84-cb05-4306-b6f2-250e09cbd744' User entered 'None (0)'	System	05 Sep 2020 03:06:43
	System	05 Sep 2020 03:06:43

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T22:06:15', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4d0edd84-cb05-4306-b6f2-250e09cbd744' User entered 'None (0)'	System	05 Sep 2020 03:06:43
	System	05 Sep 2020 03:06:43

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T22:06:18', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4d0edd84-cb05-4306-b6f2-250e09cbd744' User entered 'None (0)'	System	05 Sep 2020 03:06:43
	System	05 Sep 2020 03:06:43

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T22:06:21', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4d0edd84-cb05-4306-b6f2-250e09cbd744' User entered 'None (0)'	System	05 Sep 2020 03:06:43
	System	05 Sep 2020 03:06:43

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T22:06:24', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4d0edd84-cb05-4306-b6f2-250e09cbd744' User entered 'None (0)'	System	05 Sep 2020 03:06:43
	System	05 Sep 2020 03:06:43

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T22:06:28', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4d0edd84-cb05-4306-b6f2-250e09cbd744' User entered 'No (N)'	System	05 Sep 2020 03:06:43
	System	05 Sep 2020 03:06:43

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-04T22:06:39', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4d0edd84-cb05-4306-b6f2-250e09cbd744' User entered '04 Sep 2020 22:06'	System	05 Sep 2020 03:06:43
	System	05 Sep 2020 03:06:43

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '04 Sep 2020 18:57'	System	04 Sep 2020 20:21:04



US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '05 Sep 2020 11:59'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 2'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-05T20:17:56', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '65623db4-f675-4b25-9822-38472545c4e8' User entered 'None (0)'	System	06 Sep 2020 01:18:36
	System	06 Sep 2020 01:18:36

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-05T20:18:00', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '65623db4-f675-4b25-9822-38472545c4e8' User entered 'None (0)'	System	06 Sep 2020 01:18:36
	System	06 Sep 2020 01:18:36

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-05T20:18:05', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '65623db4-f675-4b25-9822-38472545c4e8' User entered 'None (0)'	System	06 Sep 2020 01:18:36
	System	06 Sep 2020 01:18:36

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-05T20:18:07', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '65623db4-f675-4b25-9822-38472545c4e8' User entered 'None (0)'	System	06 Sep 2020 01:18:36
	System	06 Sep 2020 01:18:36

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-05T20:18:10', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '65623db4-f675-4b25-9822-38472545c4e8' User entered 'None (0)'	System	06 Sep 2020 01:18:36
	System	06 Sep 2020 01:18:36

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-05T20:18:12', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '65623db4-f675-4b25-9822-38472545c4e8' User entered 'None (0)'	System	06 Sep 2020 01:18:36
	System	06 Sep 2020 01:18:36



US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-05T20:18:16', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '65623db4-f675-4b25-9822-38472545c4e8' User entered 'No (N)'	System	06 Sep 2020 01:18:36
	System	06 Sep 2020 01:18:36

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-05T20:18:31', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '65623db4-f675-4b25-9822-38472545c4e8' User entered '05 Sep 2020 20:18'	System	06 Sep 2020 01:18:36
	System	06 Sep 2020 01:18:36

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '05 Sep 2020 12:00'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '06 Sep 2020 11:59'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 3'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-06T23:33:25', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'a13f0af0-85f4-4434-ace8-ab3d154566db' User entered 'None (0)'	System	07 Sep 2020 04:35:27
	System	07 Sep 2020 04:35:27

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-06T23:33:29', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'a13f0af0-85f4-4434-ace8-ab3d154566db' User entered 'None (0)'	System	07 Sep 2020 04:35:27
	System	07 Sep 2020 04:35:27

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-06T23:33:31', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'a13f0af0-85f4-4434-ace8-ab3d154566db' User entered 'None (0)'	System	07 Sep 2020 04:35:27
	System	07 Sep 2020 04:35:27



US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-06T23:33:35', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'a13f0af0-85f4-4434-ace8-ab3d154566db' User entered 'None (0)'	System	07 Sep 2020 04:35:27
	System	07 Sep 2020 04:35:27

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-06T23:33:39', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'a13f0af0-85f4-4434-ace8-ab3d154566db' User entered 'None (0)'	System	07 Sep 2020 04:35:27
	System	07 Sep 2020 04:35:27

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-06T23:33:42', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'a13f0af0-85f4-4434-ace8-ab3d154566db' User entered 'None (0)'	System	07 Sep 2020 04:35:27
	System	07 Sep 2020 04:35:27

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-06T23:33:48', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'a13f0af0-85f4-4434-ace8-ab3d154566db' User entered 'No (N)'	System	07 Sep 2020 04:35:27
	System	07 Sep 2020 04:35:27

**US3782153**

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

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

**Generated On: 10 Jun 2021 09:44:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-06T23:33:58', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'a13f0af0-85f4-4434-ace8-ab3d154566db' User entered '06 Sep 2020 23:33'	System	07 Sep 2020 04:35:27
	System	07 Sep 2020 04:35:27

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '06 Sep 2020 12:00'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '07 Sep 2020 11:59'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 4'	System	04 Sep 2020 20:21:04



US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-07T23:04:35', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'dc780a5b-a7a4-4f0d-b12f-64289c46495d' User entered 'None (0)'	System	08 Sep 2020 04:05:14
	System	08 Sep 2020 04:05:14

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-07T23:04:39', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'dc780a5b-a7a4-4f0d-b12f-64289c46495d' User entered 'None (0)'	System	08 Sep 2020 04:05:14
	System	08 Sep 2020 04:05:14

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-07T23:04:42', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'dc780a5b-a7a4-4f0d-b12f-64289c46495d' User entered 'None (0)'	System	08 Sep 2020 04:05:14
	System	08 Sep 2020 04:05:14

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-07T23:04:49', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'dc780a5b-a7a4-4f0d-b12f-64289c46495d' User entered 'None (0)'	System	08 Sep 2020 04:05:14
	System	08 Sep 2020 04:05:14

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-07T23:04:51', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'dc780a5b-a7a4-4f0d-b12f-64289c46495d' User entered 'None (0)'	System	08 Sep 2020 04:05:14
	System	08 Sep 2020 04:05:14

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-07T23:04:55', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'dc780a5b-a7a4-4f0d-b12f-64289c46495d' User entered 'None (0)'	System	08 Sep 2020 04:05:14
	System	08 Sep 2020 04:05:14

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-07T23:04:58', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'dc780a5b-a7a4-4f0d-b12f-64289c46495d' User entered 'No (N)'	System	08 Sep 2020 04:05:14
	System	08 Sep 2020 04:05:14

**US3782153**

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

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

**Generated On: 10 Jun 2021 09:44:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-07T23:05:10', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'dc780a5b-a7a4-4f0d-b12f-64289c46495d' User entered '07 Sep 2020 23:05'	System	08 Sep 2020 04:05:14
	System	08 Sep 2020 04:05:14



US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '07 Sep 2020 12:00'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '08 Sep 2020 11:59'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 5'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-08T22:16:07', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '13372045-49b8-4841-b484-df1349e8d43d' User entered 'None (0)'	System	09 Sep 2020 03:16:40
	System	09 Sep 2020 03:16:40

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-08T22:16:09', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '13372045-49b8-4841-b484-df1349e8d43d' User entered 'None (0)'	System	09 Sep 2020 03:16:40
	System	09 Sep 2020 03:16:40

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-08T22:16:11', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '13372045-49b8-4841-b484-df1349e8d43d' User entered 'None (0)'	System	09 Sep 2020 03:16:40
	System	09 Sep 2020 03:16:40

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-08T22:16:14', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '13372045-49b8-4841-b484-df1349e8d43d' User entered 'None (0)'	System	09 Sep 2020 03:16:40
	System	09 Sep 2020 03:16:40

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-08T22:16:18', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '13372045-49b8-4841-b484-df1349e8d43d' User entered 'None (0)'	System	09 Sep 2020 03:16:40
	System	09 Sep 2020 03:16:40



US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-08T22:16:21', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '13372045-49b8-4841-b484-df1349e8d43d' User entered 'None (0)'	System	09 Sep 2020 03:16:40
	System	09 Sep 2020 03:16:40

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-08T22:16:26', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '13372045-49b8-4841-b484-df1349e8d43d' User entered 'No (N)'	System	09 Sep 2020 03:16:40
	System	09 Sep 2020 03:16:40

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-08T22:16:37', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '13372045-49b8-4841-b484-df1349e8d43d' User entered '08 Sep 2020 22:16'	System	09 Sep 2020 03:16:40
	System	09 Sep 2020 03:16:40

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '08 Sep 2020 12:00'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '09 Sep 2020 11:59'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 6'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-09T22:21:47', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0005eddc-cbeb-4651-9f62-046eb127331e' User entered 'None (0)'	System	10 Sep 2020 03:22:09
	System	10 Sep 2020 03:22:09

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-09T22:21:50', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0005eddc-cbeb-4651-9f62-046eb127331e' User entered 'None (0)'	System	10 Sep 2020 03:22:09
	System	10 Sep 2020 03:22:09



US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-09T22:21:52', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0005eddc-cbeb-4651-9f62-046eb127331e' User entered 'None (0)'	System	10 Sep 2020 03:22:09
	System	10 Sep 2020 03:22:09

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-09T22:21:54', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0005eddc-cbeb-4651-9f62-046eb127331e' User entered 'None (0)'	System	10 Sep 2020 03:22:09
	System	10 Sep 2020 03:22:09

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-09T22:21:56', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0005eddc-cbeb-4651-9f62-046eb127331e' User entered 'None (0)'	System	10 Sep 2020 03:22:09
	System	10 Sep 2020 03:22:09

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-09T22:21:58', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0005eddc-cbeb-4651-9f62-046eb127331e' User entered 'None (0)'	System	10 Sep 2020 03:22:09
	System	10 Sep 2020 03:22:09

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-09T22:22:03', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0005eddc-cbeb-4651-9f62-046eb127331e' User entered 'No (N)'	System	10 Sep 2020 03:22:09
	System	10 Sep 2020 03:22:09

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-09T22:22:06', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0005eddc-cbeb-4651-9f62-046eb127331e' User entered '09 Sep 2020 22:22'	System	10 Sep 2020 03:22:09
	System	10 Sep 2020 03:22:09

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '09 Sep 2020 12:00'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '10 Sep 2020 11:59'	System	04 Sep 2020 20:21:04



US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 7'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-10T22:13:58', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8fd0bffa-6778-42c4-a603-2add71c84cdd' User entered 'None (0)'	System	11 Sep 2020 03:14:34
	System	11 Sep 2020 03:14:34

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-10T22:14:00', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8fd0bffa-6778-42c4-a603-2add71c84cdd' User entered 'None (0)'	System	11 Sep 2020 03:14:34
	System	11 Sep 2020 03:14:34

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-10T22:14:03', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8fd0bffa-6778-42c4-a603-2add71c84cdd' User entered 'None (0)'	System	11 Sep 2020 03:14:34
	System	11 Sep 2020 03:14:34

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-10T22:14:05', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8fd0bffa-6778-42c4-a603-2add71c84cdd' User entered 'None (0)'	System	11 Sep 2020 03:14:34
	System	11 Sep 2020 03:14:34

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-10T22:14:08', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8fd0bffa-6778-42c4-a603-2add71c84cdd' User entered 'None (0)'	System	11 Sep 2020 03:14:34
	System	11 Sep 2020 03:14:34

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-10T22:14:10', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8fd0bffa-6778-42c4-a603-2add71c84cdd' User entered 'None (0)'	System	11 Sep 2020 03:14:34
	System	11 Sep 2020 03:14:34

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-10T22:14:14', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8fd0bffa-6778-42c4-a603-2add71c84cdd' User entered 'No (N)'	System	11 Sep 2020 03:14:34
	System	11 Sep 2020 03:14:34



US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-09-10T22:14:25', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8fd0bffa-6778-42c4-a603-2add71c84cdd' User entered '10 Sep 2020 22:14'	System	11 Sep 2020 03:14:34
	System	11 Sep 2020 03:14:34

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '10 Sep 2020 12:00'	System	04 Sep 2020 20:21:04

US3782153

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '11 Sep 2020 11:59'	System	04 Sep 2020 20:21:04

**US3782153**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:44:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:08:04

**US3782153**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:08:04

US3782153

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:08:04

US3782153

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:08:04

US3782153

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 17:08:10



**US3782153**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:44:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'I'	System	11 Sep 2020 17:08:10

**US3782153**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:44:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	18 Sep 2020 18:09:00

US3782153

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '18 Sep 2020'	Carlton Griffin (b) (4)	18 Sep 2020 18:09:00

US3782153

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	18 Sep 2020 18:09:00

US3782153

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) Carlton Griffin (b) (4)	18 Sep 2020 18:09:00

US3782153

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	18 Sep 2020 18:09:10

US3782153

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:15

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'I'	System	18 Sep 2020 18:09:10

**US3782153**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:44:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	25 Sep 2020 19:32:40



US3782153

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '25 Sep 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	25 Sep 2020 19:32:40

US3782153

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	25 Sep 2020 19:32:40

US3782153

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) Carlton Griffin (b) (4)	25 Sep 2020 19:32:40
	(b) (4)	

US3782153

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	25 Sep 2020 19:32:31

**US3782153**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:44:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'I'	System	25 Sep 2020 19:32:31

US3782153

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:14:47

US3782153

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:14:47

US3782153

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:15

[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 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:14:47



US3782153

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:15

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'VISIT2'	System	06 Oct 2020 14:14:47

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	06 Oct 2020 14:15:44

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:15:44

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:15:44

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '08:38'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:15:44

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered '6 Oct 2020 08:38'	System	06 Oct 2020 14:15:44

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '97.7' F	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:15:44

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:15:44



US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:15:44

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '65'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:15:44

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'bpm'	System	06 Oct 2020 14:15:44

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '16'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:15:44

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'breaths/min'	System	06 Oct 2020 14:15:44

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '110'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:15:44

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'mmHg'	System	06 Oct 2020 14:15:44

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '64'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:15:44



US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 10 Jun 2021 09:44:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'mmHg'	System	06 Oct 2020 14:15:44

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	06 Oct 2020 15:17:09

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Oct 2020 15:17:17
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Oct 2020 15:17:17
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Oct 2020 15:17:09
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 15:17:09

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:17:09

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '09:51'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:17:09

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered '6 Oct 2020 09:51'	System	06 Oct 2020 15:17:09

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User closed query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	06 Oct 2020 15:37:39
Query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	06 Oct 2020 15:37:39
User entered '97.8' F reason for change: Data Entry Error	Carlton Griffin (b) (4)	06 Oct 2020 15:37:39
User opened query 'Temperature reported is out of range >41.7C (107F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4)	06 Oct 2020 15:17:09
User entered '97.8' C	System	06 Oct 2020 15:17:09
	(b) (4), (b) (6)	06 Oct 2020 15:17:09

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:17:09



US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:17:09

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '64'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:17:09

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'bpm'	System	06 Oct 2020 15:17:09

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '16'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:17:09

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'breaths/min'	System	06 Oct 2020 15:17:09

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '114'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:17:09

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'mmHg'	System	06 Oct 2020 15:17:09

US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '69'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:17:09



US3782153

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 10 Jun 2021 09:44:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'mmHg'	System	06 Oct 2020 15:17:09

US3782153

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:44:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:37:36

US3782153

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:44:15

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:37:36

US3782153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:44:15

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:39:54

US3782153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:44:15

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:39:54

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:44:15

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 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 14:39:54

US3782153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:44:15

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'MRNA-1273 OR PLACEBO'	System	06 Oct 2020 14:39:54

US3782153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:44:15

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:39:54



US3782153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:44:15

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '09:19'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:39:54

US3782153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:44:15

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered '6 Oct 2020 09:19'	System	06 Oct 2020 14:39:54

US3782153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:44:15

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:39:54

US3782153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:44:15

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'ONCE'	System	06 Oct 2020 14:39:54

US3782153

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 10 Jun 2021 09:44:15

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'INTRAMUSCULAR'	System	06 Oct 2020 14:39:54

US3782153

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:38:22

US3782153

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:38:22

US3782153

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '08:41'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:38:22



**US3782153**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:44:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered '6 Oct 2020 08:41'	System	06 Oct 2020 14:38:22

US3782153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 10 Jun 2021 09:44:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '6 Oct 2020'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:38:49

**US3782153**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	06 Oct 2020 14:38:49

US3782153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 10 Jun 2021 09:44:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:38:49

**US3782153**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '08:43'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:38:49

**US3782153**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered '6 Oct 2020 08:43'	System	06 Oct 2020 14:38:49

**US3782153**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 10 Jun 2021 09:44:15**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	06 Oct 2020 14:38:49

US3782153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:44:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:38:49



US3782153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:44:15

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4), (b) (6)	06 Oct 2020 14:38:49

US3782153

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 10 Jun 2021 09:44:15

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered empty.	System	06 Oct 2020 14:38:49

US3782153

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Oct 2020 14:38:56

**US3782153**

**Folder: Visit 2 Day 29 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:44:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'I'	System	06 Oct 2020 14:38:56

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T09:52:31', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '658649d4-87d5-46f5-8fed-ee90a5a5e34d' User entered 'Yes (Y)'	System	06 Oct 2020 14:53:02
	System	06 Oct 2020 14:53:02

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T09:52:39', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '658649d4-87d5-46f5-8fed-ee90a5a5e34d' User entered '97.8'	System	06 Oct 2020 14:53:02
	System	06 Oct 2020 14:53:02

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T09:52:50', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '658649d4-87d5-46f5-8fed-ee90a5a5e34d' User entered 'No (N)'	System	06 Oct 2020 14:53:02
	System	06 Oct 2020 14:53:02



US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T09:52:57', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '658649d4-87d5-46f5-8fed-ee90a5a5e34d' User entered '06 Oct 2020 09:52'	System	06 Oct 2020 14:53:02
	System	06 Oct 2020 14:53:02

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '06 Oct 2020 09:39'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '06 Oct 2020 12:09'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T22:39:06', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0458ff91-4bd6-49ca-8222-80c1cae9a6b6' User entered 'Yes (Y)'	System	07 Oct 2020 03:39:39
	System	07 Oct 2020 03:39:39

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T22:39:12', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0458ff91-4bd6-49ca-8222-80c1cae9a6b6' User entered '97.2'	System	07 Oct 2020 03:39:39
	System	07 Oct 2020 03:39:39

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T22:39:16', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0458ff91-4bd6-49ca-8222-80c1cae9a6b6'	System	07 Oct 2020 03:39:39
User entered 'No (N)'	System	07 Oct 2020 03:39:39

**US3782153**

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

**Form: Temperature\_Day(1/2)**

**Generated On: 10 Jun 2021 09:44:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T22:39:35', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0458ff91-4bd6-49ca-8222-80c1cae9a6b6' User entered '06 Oct 2020 22:39'	System	07 Oct 2020 03:39:39
	System	07 Oct 2020 03:39:39



US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '06 Oct 2020 13:04'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 2'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:44:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-07T22:23:50', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '89b0ed10-d179-4870-ae2e-b4d29a4e2f4b' User entered 'Yes (Y)'	System	08 Oct 2020 03:24:16
	System	08 Oct 2020 03:24:16

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:44:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-07T22:24:01', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '89b0ed10-d179-4870-ae2e-b4d29a4e2f4b' User entered '97.4'	System	08 Oct 2020 03:24:16
	System	08 Oct 2020 03:24:16

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-07T22:24:05', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '89b0ed10-d179-4870-ae2e-b4d29a4e2f4b' User entered 'No (N)'	System	08 Oct 2020 03:24:16
	System	08 Oct 2020 03:24:16

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:44:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-07T22:24:12', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '89b0ed10-d179-4870-ae2e-b4d29a4e2f4b' User entered '07 Oct 2020 22:24'	System	08 Oct 2020 03:24:16
	System	08 Oct 2020 03:24:16

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 14:39:54



US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 3'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:44:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-08T22:24:24', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'cc83b6e5-147a-4c3f-ba83-ca2af5916f1d' User entered 'Yes (Y)'	System	09 Oct 2020 03:24:52
	System	09 Oct 2020 03:24:52

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:44:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-08T22:24:33', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'cc83b6e5-147a-4c3f-ba83-ca2af5916f1d' User entered '97.6'	System	09 Oct 2020 03:24:52
	System	09 Oct 2020 03:24:52

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-08T22:24:38', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'cc83b6e5-147a-4c3f-ba83-ca2af5916f1d' User entered 'No (N)'	System	09 Oct 2020 03:24:52
	System	09 Oct 2020 03:24:52

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:44:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-08T22:24:46', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'cc83b6e5-147a-4c3f-ba83-ca2af5916f1d' User entered '08 Oct 2020 22:24'	System	09 Oct 2020 03:24:52
	System	09 Oct 2020 03:24:52

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 14:39:54



US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 4'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:44:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-09T21:57:35', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'cb4d2f40-27bd-4f14-8a2e-c711befa07ae' User entered 'Yes (Y)'	System	10 Oct 2020 02:58:21
	System	10 Oct 2020 02:58:21

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:44:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-09T21:57:41', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'cb4d2f40-27bd-4f14-8a2e-c711befa07ae' User entered '96.7'	System	10 Oct 2020 02:58:21
	System	10 Oct 2020 02:58:21

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-09T21:58:07', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'cb4d2f40-27bd-4f14-8a2e-c711befa07ae' User entered 'No (N)'	System	10 Oct 2020 02:58:21
	System	10 Oct 2020 02:58:21

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:44:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-09T21:58:17', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'cb4d2f40-27bd-4f14-8a2e-c711befa07ae' User entered '09 Oct 2020 21:58'	System	10 Oct 2020 02:58:21
	System	10 Oct 2020 02:58:21

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 5'	System	06 Oct 2020 14:39:54



US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:44:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-10T23:16:25', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'c17c8301-993d-41f1-909a-fcc97b38817f' User entered 'Yes (Y)'	System	11 Oct 2020 15:37:20
	System	11 Oct 2020 15:37:20

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:44:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-10T23:16:31', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'c17c8301-993d-41f1-909a-fcc97b38817f' User entered '97.9'	System	11 Oct 2020 15:37:20
	System	11 Oct 2020 15:37:20

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-10T23:16:35', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'c17c8301-993d-41f1-909a-fcc97b38817f' User entered 'No (N)'	System	11 Oct 2020 15:37:20
	System	11 Oct 2020 15:37:20

**US3782153**

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

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

**Generated On: 10 Jun 2021 09:44:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-10T23:16:41', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'c17c8301-993d-41f1-909a-fcc97b38817f' User entered '10 Oct 2020 23:16'	System	11 Oct 2020 15:37:20
	System	11 Oct 2020 15:37:20

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 6'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:44:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-11T22:09:56', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '65d88db4-cb34-4a72-ad50-0b1e884f00e5' User entered 'Yes (Y)'	System	12 Oct 2020 03:10:38
	System	12 Oct 2020 03:10:38



US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:44:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-11T22:10:01', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '65d88db4-cb34-4a72-ad50-0b1e884f00e5' User entered '97.2'	System	12 Oct 2020 03:10:38
	System	12 Oct 2020 03:10:38

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-11T22:10:04', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '65d88db4-cb34-4a72-ad50-0b1e884f00e5' User entered 'No (N)'	System	12 Oct 2020 03:10:38
	System	12 Oct 2020 03:10:38

**US3782153**

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

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

**Generated On: 10 Jun 2021 09:44:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-11T22:10:12', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '65d88db4-cb34-4a72-ad50-0b1e884f00e5' User entered '11 Oct 2020 22:10'	System	12 Oct 2020 03:10:38
	System	12 Oct 2020 03:10:38

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 14:39:54

**US3782153**

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

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

**Generated On: 10 Jun 2021 09:44:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 7'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:44:15

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-13T06:40:45', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8641cdd4-cf83-4d7a-9518-063d71c54322' User entered 'Yes (Y)'	System	13 Oct 2020 11:41:10
	System	13 Oct 2020 11:41:10

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:44:15

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-13T06:40:59', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8641cdd4-cf83-4d7a-9518-063d71c54322' User entered '97.4'	System	13 Oct 2020 11:41:10
	System	13 Oct 2020 11:41:10



US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-13T06:41:02', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8641cdd4-cf83-4d7a-9518-063d71c54322'	System	13 Oct 2020 11:41:10
User entered 'No (N)'	System	13 Oct 2020 11:41:10

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:44:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-13T06:41:07', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8641cdd4-cf83-4d7a-9518-063d71c54322' User entered '13 Oct 2020 06:41'	System	13 Oct 2020 11:41:10
	System	13 Oct 2020 11:41:10

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T09:53:08', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'edafee5e-f7cb-471f-97d4-d8da2cb8cb44' User entered 'None (1)'	System	06 Oct 2020 14:53:38
	System	06 Oct 2020 14:53:38

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T09:53:14', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'edafee5e-f7cb-471f-97d4-d8da2cb8cb44' User entered 'No (N)'	System	06 Oct 2020 14:53:38
	System	06 Oct 2020 14:53:38

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T09:53:19', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'edafee5e-f7cb-471f-97d4-d8da2cb8cb44' User entered 'No (N)'	System	06 Oct 2020 14:53:38
	System	06 Oct 2020 14:53:38



US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T09:53:22', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'edafee5e-f7cb-471f-97d4-d8da2cb8cb44'	System	06 Oct 2020 14:53:38
User entered 'None (1)'	System	06 Oct 2020 14:53:38

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T09:53:35', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'edafee5e-f7cb-471f-97d4-d8da2cb8cb44' User entered '06 Oct 2020 09:53'	System	06 Oct 2020 14:53:38
	System	06 Oct 2020 14:53:38

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '06 Oct 2020 09:39'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '06 Oct 2020 12:09'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T22:39:48', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'c53eceed-fc2e-4c7a-ae9b-a44f5df37358'	System	07 Oct 2020 03:42:18
User entered 'Does not interfere with activity (2)'	System	07 Oct 2020 03:42:18

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T22:39:51', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'c53eceed-fc2e-4c7a-ae9b-a44f5df37358'	System	07 Oct 2020 03:42:18
User entered 'No (N)'	System	07 Oct 2020 03:42:18

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T22:40:35', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'c53eceed-fc2e-4c7a-ae9b-a44f5df37358'	System	07 Oct 2020 03:42:18
User entered 'Yes (Y)'	System	07 Oct 2020 03:42:18



US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T22:41:57', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'c53eceed-fc2e-4c7a-ae9b-a44f5df37358' User entered '60'	System	07 Oct 2020 03:42:18
	System	07 Oct 2020 03:42:18

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T22:42:03', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'c53eceed-fc2e-4c7a-ae9b-a44f5df37358'	System	07 Oct 2020 03:42:18
User entered 'None (1)'	System	07 Oct 2020 03:42:18

**US3782153**

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

**Form: Injection Site\_Day(1/2)**

**Generated On: 10 Jun 2021 09:44:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T22:42:15', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'c53eceed-fc2e-4c7a-ae9b-a44f5df37358' User entered '06 Oct 2020 22:42'	System	07 Oct 2020 03:42:18
	System	07 Oct 2020 03:42:18

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '06 Oct 2020 13:04'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 2'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-07T22:24:36', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'a6913ef6-be0b-4155-93c6-b98e23022b11'	System	08 Oct 2020 03:25:16
User entered 'Does not interfere with activity (2)'	System	08 Oct 2020 03:25:16

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:44:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-07T22:24:40', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'a6913ef6-be0b-4155-93c6-b98e23022b11' User entered 'No (N)'	System	08 Oct 2020 03:25:16
	System	08 Oct 2020 03:25:16



US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-07T22:24:51', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'a6913ef6-be0b-4155-93c6-b98e23022b11' User entered 'No (N)'	System	08 Oct 2020 03:25:16
	System	08 Oct 2020 03:25:16

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-07T22:24:58', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'a6913ef6-be0b-4155-93c6-b98e23022b11' User entered 'None (1)'	System	08 Oct 2020 03:25:16
	System	08 Oct 2020 03:25:16

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:44:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-07T22:25:10', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'a6913ef6-be0b-4155-93c6-b98e23022b11' User entered '07 Oct 2020 22:25'	System	08 Oct 2020 03:25:16
	System	08 Oct 2020 03:25:16

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 3'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-08T22:25:03', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'a452a211-e6e6-41a7-a649-dc417c79a56b'	System	09 Oct 2020 03:25:30
User entered 'Does not interfere with activity (2)'	System	09 Oct 2020 03:25:30

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:44:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-08T22:25:06', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'a452a211-e6e6-41a7-a649-dc417c79a56b' User entered 'No (N)'	System	09 Oct 2020 03:25:30
	System	09 Oct 2020 03:25:30



US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-08T22:25:09', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'a452a211-e6e6-41a7-a649-dc417c79a56b' User entered 'No (N)'	System	09 Oct 2020 03:25:30
	System	09 Oct 2020 03:25:30

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-08T22:25:16', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'a452a211-e6e6-41a7-a649-dc417c79a56b' User entered 'None (1)'	System	09 Oct 2020 03:25:30
	System	09 Oct 2020 03:25:30

**US3782153**

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

**Form: Injection Site\_Day(3)**

**Generated On: 10 Jun 2021 09:44:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-08T22:25:26', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'a452a211-e6e6-41a7-a649-dc417c79a56b' User entered '08 Oct 2020 22:25'	System	09 Oct 2020 03:25:30
	System	09 Oct 2020 03:25:30

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 4'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-09T21:58:23', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8388fc23-0953-43e2-ab01-9664511e42be' User entered 'None (1)'	System	10 Oct 2020 02:58:49
	System	10 Oct 2020 02:58:49

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:44:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-09T21:58:26', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8388fc23-0953-43e2-ab01-9664511e42be' User entered 'No (N)'	System	10 Oct 2020 02:58:49
	System	10 Oct 2020 02:58:49



US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-09T21:58:29', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8388fc23-0953-43e2-ab01-9664511e42be' User entered 'No (N)'	System	10 Oct 2020 02:58:49
	System	10 Oct 2020 02:58:49

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-09T21:58:36', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8388fc23-0953-43e2-ab01-9664511e42be' User entered 'None (1)'	System	10 Oct 2020 02:58:49
	System	10 Oct 2020 02:58:49

**US3782153**

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

**Form: Injection Site\_Day(4)**

**Generated On: 10 Jun 2021 09:44:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-09T21:58:45', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8388fc23-0953-43e2-ab01-9664511e42be' User entered '09 Oct 2020 21:58'	System	10 Oct 2020 02:58:49
	System	10 Oct 2020 02:58:49

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 5'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-10T23:16:47', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '30c9cb01-5391-42f5-adcf-815c37a0dbbc'	System	11 Oct 2020 15:37:22
User entered 'None (1)'	System	11 Oct 2020 15:37:22

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:44:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-10T23:16:51', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '30c9cb01-5391-42f5-adcf-815c37a0dbbc' User entered 'No (N)'	System	11 Oct 2020 15:37:22
	System	11 Oct 2020 15:37:22



US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-10T23:16:54', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '30c9cb01-5391-42f5-adcf-815c37a0dbbc' User entered 'No (N)'	System	11 Oct 2020 15:37:22
	System	11 Oct 2020 15:37:22

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-10T23:16:59', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '30c9cb01-5391-42f5-adcf-815c37a0dbbc' User entered 'None (1)'	System	11 Oct 2020 15:37:22
	System	11 Oct 2020 15:37:22

**US3782153**

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

**Form: Injection Site\_Day(5)**

**Generated On: 10 Jun 2021 09:44:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-10T23:17:08', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '30c9cb01-5391-42f5-adcf-815c37a0dbbc' User entered '10 Oct 2020 23:17'	System	11 Oct 2020 15:37:22
	System	11 Oct 2020 15:37:22

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 6'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-11T22:10:16', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '09ebc4f3-aadf-41d0-9b56-26cdb236c489'	System	12 Oct 2020 03:11:01
User entered 'None (1)'	System	12 Oct 2020 03:11:01

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:44:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-11T22:10:19', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '09ebc4f3-aadf-41d0-9b56-26cdb236c489'	System	12 Oct 2020 03:11:01
User entered 'No (N)'	System	12 Oct 2020 03:11:01



US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-11T22:10:22', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '09ebc4f3-aadf-41d0-9b56-26cdb236c489' User entered 'No (N)'	System	12 Oct 2020 03:11:01
	System	12 Oct 2020 03:11:01

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-11T22:10:25', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '09ebc4f3-aadf-41d0-9b56-26cdb236c489'	System	12 Oct 2020 03:11:01
User entered 'None (1)'	System	12 Oct 2020 03:11:01

**US3782153**

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

**Form: Injection Site\_Day(6)**

**Generated On: 10 Jun 2021 09:44:15**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-11T22:10:31', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '09ebc4f3-aadf-41d0-9b56-26cdb236c489' User entered '11 Oct 2020 22:10'	System	12 Oct 2020 03:11:01
	System	12 Oct 2020 03:11:01

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 7'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-13T06:41:13', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8a5ba48e-2721-4da9-b984-f3f387f6b191'	System	13 Oct 2020 11:41:34
User entered 'None (1)'	System	13 Oct 2020 11:41:34

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:44:15

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-13T06:41:17', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8a5ba48e-2721-4da9-b984-f3f387f6b191' User entered 'No (N)'	System	13 Oct 2020 11:41:34
	System	13 Oct 2020 11:41:34



US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-13T06:41:19', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8a5ba48e-2721-4da9-b984-f3f387f6b191' User entered 'No (N)'	System	13 Oct 2020 11:41:34
	System	13 Oct 2020 11:41:34

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:44:15

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-13T06:41:23', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8a5ba48e-2721-4da9-b984-f3f387f6b191'	System	13 Oct 2020 11:41:34
User entered 'None (1)'	System	13 Oct 2020 11:41:34

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:44:15

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-13T06:41:30', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8a5ba48e-2721-4da9-b984-f3f387f6b191' User entered '13 Oct 2020 06:41'	System	13 Oct 2020 11:41:34
	System	13 Oct 2020 11:41:34

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T09:54:00', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '55688267-2e62-439f-af90-d237dcd8f184' User entered 'None (0)'	System	06 Oct 2020 14:54:36
	System	06 Oct 2020 14:54:36

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T09:54:03', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '55688267-2e62-439f-af90-d237dcd8f184' User entered 'None (0)'	System	06 Oct 2020 14:54:36
	System	06 Oct 2020 14:54:36



US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T09:54:05', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '55688267-2e62-439f-af90-d237dcd8f184' User entered 'None (0)'	System	06 Oct 2020 14:54:36
	System	06 Oct 2020 14:54:36

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T09:54:08', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '55688267-2e62-439f-af90-d237dcd8f184' User entered 'None (0)'	System	06 Oct 2020 14:54:36
	System	06 Oct 2020 14:54:36

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T09:54:10', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '55688267-2e62-439f-af90-d237dcd8f184' User entered 'None (0)'	System	06 Oct 2020 14:54:36
	System	06 Oct 2020 14:54:36

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T09:54:13', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '55688267-2e62-439f-af90-d237dcd8f184' User entered 'None (0)'	System	06 Oct 2020 14:54:36
	System	06 Oct 2020 14:54:36

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T09:54:23', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '55688267-2e62-439f-af90-d237dcd8f184' User entered 'No (N)'	System	06 Oct 2020 14:54:36
	System	06 Oct 2020 14:54:36

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T09:54:34', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '55688267-2e62-439f-af90-d237dcd8f184' User entered '06 Oct 2020 09:54'	System	06 Oct 2020 14:54:36
	System	06 Oct 2020 14:54:36

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '06 Oct 2020 09:39'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '06 Oct 2020 12:09'	System	06 Oct 2020 14:39:54



US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 1, after vaccination (at home)'	System	06 Oct 2020 14:39:54

**US3782153**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:44:15**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T22:42:20', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'f36dab6f-26a7-447b-a931-7a356c3bad4b' User entered 'None (0)'	System	07 Oct 2020 03:43:11
	System	07 Oct 2020 03:43:11

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T22:42:23', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'f36dab6f-26a7-447b-a931-7a356c3bad4b' User entered 'None (0)'	System	07 Oct 2020 03:43:11
	System	07 Oct 2020 03:43:11

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T22:42:26', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'f36dab6f-26a7-447b-a931-7a356c3bad4b' User entered 'None (0)'	System	07 Oct 2020 03:43:11
	System	07 Oct 2020 03:43:11

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T22:42:30', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'f36dab6f-26a7-447b-a931-7a356c3bad4b' User entered 'None (0)'	System	07 Oct 2020 03:43:11
	System	07 Oct 2020 03:43:11

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T22:42:32', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'f36dab6f-26a7-447b-a931-7a356c3bad4b' User entered 'None (0)'	System	07 Oct 2020 03:43:11
	System	07 Oct 2020 03:43:11

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T22:42:35', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'f36dab6f-26a7-447b-a931-7a356c3bad4b' User entered 'None (0)'	System	07 Oct 2020 03:43:11
	System	07 Oct 2020 03:43:11

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T22:42:41', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'f36dab6f-26a7-447b-a931-7a356c3bad4b' User entered 'No (N)'	System	07 Oct 2020 03:43:11
	System	07 Oct 2020 03:43:11



**US3782153**

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

**Form: General\_Day(1/2)**

**Generated On: 10 Jun 2021 09:44:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-06T22:42:57', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'f36dab6f-26a7-447b-a931-7a356c3bad4b' User entered '06 Oct 2020 22:42'	System	07 Oct 2020 03:43:11
	System	07 Oct 2020 03:43:11

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '06 Oct 2020 13:04'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '07 Oct 2020 11:59'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 2'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-07T22:25:36', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '91497752-c306-4c7a-8bba-4d3e91a0bb0b' User entered 'None (0)'	System	08 Oct 2020 03:27:07
	System	08 Oct 2020 03:27:07

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-07T22:25:54', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '91497752-c306-4c7a-8bba-4d3e91a0bb0b' User entered 'Some interference with activity (2)'	System	08 Oct 2020 03:27:07
	System	08 Oct 2020 03:27:07

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-07T22:26:03', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '91497752-c306-4c7a-8bba-4d3e91a0bb0b' User entered 'Some interference with activity (2)'	System	08 Oct 2020 03:27:07
	System	08 Oct 2020 03:27:07

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-07T22:26:45', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '91497752-c306-4c7a-8bba-4d3e91a0bb0b' User entered 'Some interference with activity (2)'	System	08 Oct 2020 03:27:07
	System	08 Oct 2020 03:27:07



US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-07T22:26:13', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '91497752-c306-4c7a-8bba-4d3e91a0bb0b' User entered 'None (0)'	System	08 Oct 2020 03:27:07
	System	08 Oct 2020 03:27:07

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-07T22:26:17', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '91497752-c306-4c7a-8bba-4d3e91a0bb0b' User entered 'None (0)'	System	08 Oct 2020 03:27:07
	System	08 Oct 2020 03:27:07

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-07T22:26:20', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '91497752-c306-4c7a-8bba-4d3e91a0bb0b' User entered 'No (N)'	System	08 Oct 2020 03:27:07
	System	08 Oct 2020 03:27:07

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-07T22:26:58', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '91497752-c306-4c7a-8bba-4d3e91a0bb0b' User entered '07 Oct 2020 22:26'	System	08 Oct 2020 03:27:07
	System	08 Oct 2020 03:27:07

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '07 Oct 2020 12:00'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '08 Oct 2020 11:59'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 3'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-08T22:25:31', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'e0fe42dc-e977-4396-9af1-e895aeb6a0fb' User entered 'None (0)'	System	09 Oct 2020 03:26:18
	System	09 Oct 2020 03:26:18



US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-08T22:25:35', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'e0fe42dc-e977-4396-9af1-e895aeb6a0fb' User entered 'None (0)'	System	09 Oct 2020 03:26:18
	System	09 Oct 2020 03:26:18

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-08T22:25:40', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'e0fe42dc-e977-4396-9af1-e895aeb6a0fb' User entered 'None (0)'	System	09 Oct 2020 03:26:18
	System	09 Oct 2020 03:26:18

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-08T22:25:44', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'e0fe42dc-e977-4396-9af1-e895aeb6a0fb' User entered 'None (0)'	System	09 Oct 2020 03:26:18
	System	09 Oct 2020 03:26:18

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-08T22:25:47', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'e0fe42dc-e977-4396-9af1-e895aeb6a0fb' User entered 'None (0)'	System	09 Oct 2020 03:26:18
	System	09 Oct 2020 03:26:18

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-08T22:25:49', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'e0fe42dc-e977-4396-9af1-e895aeb6a0fb' User entered 'None (0)'	System	09 Oct 2020 03:26:18
	System	09 Oct 2020 03:26:18

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-08T22:25:52', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'e0fe42dc-e977-4396-9af1-e895aeb6a0fb' User entered 'No (N)'	System	09 Oct 2020 03:26:18
	System	09 Oct 2020 03:26:18

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-08T22:26:11', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'e0fe42dc-e977-4396-9af1-e895aeb6a0fb' User entered '08 Oct 2020 22:26'	System	09 Oct 2020 03:26:18
	System	09 Oct 2020 03:26:18

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '08 Oct 2020 12:00'	System	06 Oct 2020 14:39:54



US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '09 Oct 2020 11:59'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 4'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-09T21:58:53', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '65ec6925-2372-4134-a60d-f94c1a632194' User entered 'None (0)'	System	10 Oct 2020 02:59:25
	System	10 Oct 2020 02:59:25

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-09T21:58:55', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '65ec6925-2372-4134-a60d-f94c1a632194' User entered 'None (0)'	System	10 Oct 2020 02:59:25
	System	10 Oct 2020 02:59:25

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-09T21:58:58', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '65ec6925-2372-4134-a60d-f94c1a632194' User entered 'None (0)'	System	10 Oct 2020 02:59:25
	System	10 Oct 2020 02:59:25

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-09T21:59:01', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '65ec6925-2372-4134-a60d-f94c1a632194' User entered 'None (0)'	System	10 Oct 2020 02:59:25
	System	10 Oct 2020 02:59:25

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-09T21:59:03', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '65ec6925-2372-4134-a60d-f94c1a632194' User entered 'None (0)'	System	10 Oct 2020 02:59:25
	System	10 Oct 2020 02:59:25

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-09T21:59:06', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '65ec6925-2372-4134-a60d-f94c1a632194' User entered 'None (0)'	System	10 Oct 2020 02:59:25
	System	10 Oct 2020 02:59:25



US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-09T21:59:08', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '65ec6925-2372-4134-a60d-f94c1a632194' User entered 'No (N)'	System	10 Oct 2020 02:59:25
	System	10 Oct 2020 02:59:25

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-09T21:59:20', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '65ec6925-2372-4134-a60d-f94c1a632194' User entered '09 Oct 2020 21:59'	System	10 Oct 2020 02:59:25
	System	10 Oct 2020 02:59:25

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '09 Oct 2020 12:00'	System	06 Oct 2020 14:39:54

**US3782153**

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

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

**Generated On: 10 Jun 2021 09:44:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '10 Oct 2020 11:59'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 5'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-10T23:17:12', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '156677d3-b7d4-4280-a8cb-b57e89b5f94c' User entered 'None (0)'	System	11 Oct 2020 15:37:21
	System	11 Oct 2020 15:37:21

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-10T23:17:15', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '156677d3-b7d4-4280-a8cb-b57e89b5f94c' User entered 'None (0)'	System	11 Oct 2020 15:37:21
	System	11 Oct 2020 15:37:21

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-10T23:17:18', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '156677d3-b7d4-4280-a8cb-b57e89b5f94c' User entered 'None (0)'	System	11 Oct 2020 15:37:21
	System	11 Oct 2020 15:37:21



US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-10T23:17:21', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '156677d3-b7d4-4280-a8cb-b57e89b5f94c' User entered 'None (0)'	System	11 Oct 2020 15:37:21
	System	11 Oct 2020 15:37:21

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-10T23:17:24', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '156677d3-b7d4-4280-a8cb-b57e89b5f94c' User entered 'None (0)'	System	11 Oct 2020 15:37:21
	System	11 Oct 2020 15:37:21

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-10T23:17:27', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '156677d3-b7d4-4280-a8cb-b57e89b5f94c' User entered 'None (0)'	System	11 Oct 2020 15:37:21
	System	11 Oct 2020 15:37:21

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-10T23:17:31', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '156677d3-b7d4-4280-a8cb-b57e89b5f94c' User entered 'No (N)'	System	11 Oct 2020 15:37:21
	System	11 Oct 2020 15:37:21

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-10T23:17:44', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '156677d3-b7d4-4280-a8cb-b57e89b5f94c' User entered '10 Oct 2020 23:17'	System	11 Oct 2020 15:37:21
	System	11 Oct 2020 15:37:21

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '10 Oct 2020 12:00'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 10 Jun 2021 09:44:15

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '11 Oct 2020 11:59'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 6'	System	06 Oct 2020 14:39:54



US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-11T22:10:35', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '6b92c869-01cd-4603-83d7-aada6a81d05f' User entered 'None (0)'	System	12 Oct 2020 03:11:04
	System	12 Oct 2020 03:11:04

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-11T22:10:37', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '6b92c869-01cd-4603-83d7-aada6a81d05f' User entered 'None (0)'	System	12 Oct 2020 03:11:04
	System	12 Oct 2020 03:11:04

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-11T22:10:39', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '6b92c869-01cd-4603-83d7-aada6a81d05f' User entered 'None (0)'	System	12 Oct 2020 03:11:04
	System	12 Oct 2020 03:11:04

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-11T22:10:40', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '6b92c869-01cd-4603-83d7-aada6a81d05f' User entered 'None (0)'	System	12 Oct 2020 03:11:04
	System	12 Oct 2020 03:11:04

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-11T22:10:42', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '6b92c869-01cd-4603-83d7-aada6a81d05f' User entered 'None (0)'	System	12 Oct 2020 03:11:04
	System	12 Oct 2020 03:11:04

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-11T22:10:45', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '6b92c869-01cd-4603-83d7-aada6a81d05f' User entered 'None (0)'	System	12 Oct 2020 03:11:04
	System	12 Oct 2020 03:11:04

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-11T22:10:47', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '6b92c869-01cd-4603-83d7-aada6a81d05f' User entered 'No (N)'	System	12 Oct 2020 03:11:04
	System	12 Oct 2020 03:11:04

**US3782153**

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

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

**Generated On: 10 Jun 2021 09:44:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-11T22:10:56', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '6b92c869-01cd-4603-83d7-aada6a81d05f' User entered '11 Oct 2020 22:10'	System	12 Oct 2020 03:11:04
	System	12 Oct 2020 03:11:04



US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '11 Oct 2020 12:00'	System	06 Oct 2020 14:39:54

**US3782153**

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

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

**Generated On: 10 Jun 2021 09:44:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '12 Oct 2020 11:59'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	06 Oct 2020 14:39:54
User entered 'Day 7'	System	06 Oct 2020 14:39:54

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-13T06:41:34', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '5decbbde-4180-4089-8594-10a7d75ef64e' User entered 'None (0)'	System	13 Oct 2020 11:52:35
	System	13 Oct 2020 11:52:35

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-13T06:41:37', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '5decbbde-4180-4089-8594-10a7d75ef64e' User entered 'None (0)'	System	13 Oct 2020 11:52:35
	System	13 Oct 2020 11:52:35

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-13T06:41:39', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '5decbbde-4180-4089-8594-10a7d75ef64e' User entered 'None (0)'	System	13 Oct 2020 11:52:35
	System	13 Oct 2020 11:52:35

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-13T06:41:42', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '5decbbde-4180-4089-8594-10a7d75ef64e' User entered 'None (0)'	System	13 Oct 2020 11:52:35
	System	13 Oct 2020 11:52:35

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-13T06:41:44', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '5decbbde-4180-4089-8594-10a7d75ef64e' User entered 'None (0)'	System	13 Oct 2020 11:52:35
	System	13 Oct 2020 11:52:35



US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-13T06:41:47', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '5decbbde-4180-4089-8594-10a7d75ef64e' User entered 'None (0)'	System	13 Oct 2020 11:52:35
	System	13 Oct 2020 11:52:35

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-13T06:52:22', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '5decbbde-4180-4089-8594-10a7d75ef64e' User entered 'No (N)'	System	13 Oct 2020 11:52:35
	System	13 Oct 2020 11:52:35

**US3782153**

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

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

**Generated On: 10 Jun 2021 09:44:15**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-10-13T06:52:32', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '5decbbde-4180-4089-8594-10a7d75ef64e' User entered '13 Oct 2020 06:52'	System	13 Oct 2020 11:52:35
	System	13 Oct 2020 11:52:35

US3782153

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 10 Jun 2021 09:44:15

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '12 Oct 2020 12:00'	System	06 Oct 2020 14:39:54

**US3782153**

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

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

**Generated On: 10 Jun 2021 09:44:15**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
User entered '13 Oct 2020 11:59'	System	06 Oct 2020 14:39:54

US3782153

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:23:27

US3782153

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '13 Oct 2020'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:23:27

US3782153

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:23:27



US3782153

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:23:27

US3782153

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Oct 2020 16:23:34

**US3782153**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:44:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'I'	System	13 Oct 2020 16:23:34

**US3782153**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:44:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	20 Oct 2020 17:55:00

US3782153

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '20 Oct 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	20 Oct 2020 17:55:00

US3782153

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	20 Oct 2020 17:55:00

US3782153

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) Carlton Griffin (b) (4)	20 Oct 2020 17:55:00

US3782153

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	20 Oct 2020 17:55:07



**US3782153**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:44:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'I'	System	20 Oct 2020 17:55:07

**US3782153**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:44:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	28 Oct 2020 13:32:06

US3782153

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '27 Oct 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	28 Oct 2020 13:32:06

US3782153

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	28 Oct 2020 13:32:06

**US3782153**

**Folder: Safety Call Day 50 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:44:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) Carlton Griffin (b) (4)	28 Oct 2020 13:32:06

US3782153

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	28 Oct 2020 13:32:12

**US3782153**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:44:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'I'	System	28 Oct 2020 13:32:12

US3782153

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	03 Nov 2020 18:05:21



US3782153

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '3 Nov 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	03 Nov 2020 18:05:21

US3782153

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:15

[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 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Clinic (Clinic)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	03 Nov 2020 18:05:21

**US3782153**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:44:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'VISIT3'	System	03 Nov 2020 18:05:21

US3782153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	03 Nov 2020 18:05:55

US3782153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '3 Nov 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	03 Nov 2020 18:05:55

US3782153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '11:49'	(b) (4) Carlton Griffin (b) (4) (b) (4)	03 Nov 2020 18:05:55

**US3782153**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:44:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered '3 Nov 2020 11:49'	System	03 Nov 2020 18:05:55

US3782153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '97.5' F	(b) (4) Carlton Griffin (b) (4)	03 Nov 2020 18:05:55



US3782153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Oral (Oral)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	03 Nov 2020 18:05:55

US3782153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) Carlton Griffin (b) (4)	03 Nov 2020 18:05:55

US3782153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '67'	(b) (4) Carlton Griffin (b) (4)	03 Nov 2020 18:05:55

**US3782153**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:44:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'bpm'	System	03 Nov 2020 18:05:55

US3782153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '16'	(b) (4) Carlton Griffin (b) (4) (b) (4)	03 Nov 2020 18:05:55

US3782153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'breaths/min'	System	03 Nov 2020 18:05:55

US3782153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '108'	Carlton Griffin (b) (4)	03 Nov 2020 18:05:55

US3782153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'mmHg'	System	03 Nov 2020 18:05:55



US3782153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '67'	(b) (4) Carlton Griffin (b) (4) (b) (4)	03 Nov 2020 18:05:55

US3782153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'mmHg'	System	03 Nov 2020 18:05:55

US3782153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16

US3782153

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16

US3782153

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:44:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	03 Nov 2020 18:05:28

US3782153

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:44:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '3 Nov 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	03 Nov 2020 18:05:28

US3782153

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	03 Nov 2020 18:06:10

US3782153

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '3 Nov 2020'	(b) (4) Carlton Griffin (b) (4) (b) (4)	03 Nov 2020 18:06:10



US3782153

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '11:51'	(b) (4) Carlton Griffin (b) (4) (b) (4)	03 Nov 2020 18:06:10

**US3782153**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:44:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered '3 Nov 2020 11:51'	System	03 Nov 2020 18:06:10

US3782153

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	03 Nov 2020 18:06:14

**US3782153**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:44:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'I'	System	03 Nov 2020 18:06:14

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 64'	System	04 Sep 2020 20:21:04

US3782153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-11-07T09:08:20', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'be8e7237-ea9c-4032-adcf-d0ada4218061' User entered 'No (N)'	System	07 Nov 2020 15:08:44
	System	07 Nov 2020 15:08:44

US3782153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

Have you been exposed to someone with 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 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-11-07T09:08:26', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'be8e7237-ea9c-4032-adcf-d0ada4218061' User entered 'No (N)'	System	07 Nov 2020 15:08:44
	System	07 Nov 2020 15:08:44

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-11-07T09:08:42', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'be8e7237-ea9c-4032-adcf-d0ada4218061' User entered '07 Nov 2020 09:08:42'	System	07 Nov 2020 15:08:44
	System	07 Nov 2020 15:08:44



**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered '04 Nov 2020 00:01'	System	04 Sep 2020 20:21:04

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered '08 Nov 2020 23:59'	System	04 Sep 2020 20:21:04

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 71'	System	04 Sep 2020 20:21:04

US3782153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

[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 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-11-13T21:53:55', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '104e56f9-b6a5-46be-a110-4e3dd7ebb889'	System	14 Nov 2020 03:54:16
User entered 'No (N)'	System	14 Nov 2020 03:54:16

US3782153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

Have you been exposed to someone with 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 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-11-13T21:54:08', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '104e56f9-b6a5-46be-a110-4e3dd7ebb889'	System	14 Nov 2020 03:54:16
User entered 'No (N)'	System	14 Nov 2020 03:54:16

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-11-13T21:54:13', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '104e56f9-b6a5-46be-a110-4e3dd7ebb889' User entered '13 Nov 2020 21:54:13'	System	14 Nov 2020 03:54:16
	System	14 Nov 2020 03:54:16

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered '11 Nov 2020 00:01'	System	04 Sep 2020 20:21:04

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:02:55
Data entry locked.	System	04 Sep 2020 20:21:04
User entered '15 Nov 2020 23:59'	System	04 Sep 2020 20:21:04



US3782153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38
Data entry locked.	System	04 Sep 2020 20:21:04
User entered 'Day 78'	System	04 Sep 2020 20:21:04

US3782153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

US3782153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

US3782153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38



US3782153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

US3782153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

US3782153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38



US3782153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

US3782153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38



**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38

US3782153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38
Data entry locked.	System	04 Sep 2020 20:21:04
User entered '18 Nov 2020 00:01'	System	04 Sep 2020 20:21:04

US3782153

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 04:13:38
Data entry locked.	System	04 Sep 2020 20:21:04
User entered '22 Nov 2020 23:59'	System	04 Sep 2020 20:21:04

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 82'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-11-24T13:56:12', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '18d53d02-6b7a-4dc7-9642-ca4d26aeaae9' User entered 'No (N)'	System	24 Nov 2020 19:56:40
	System	24 Nov 2020 19:56:40

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

Have you been exposed to someone with 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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-11-24T13:56:18', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '18d53d02-6b7a-4dc7-9642-ca4d26aeaae9' User entered 'No (N)'	System	24 Nov 2020 19:56:40
	System	24 Nov 2020 19:56:40

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-11-24T13:56:37', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '18d53d02-6b7a-4dc7-9642-ca4d26aeaae9' User entered '24 Nov 2020 13:56:37'	System	24 Nov 2020 19:56:40
	System	24 Nov 2020 19:56:40



**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '22 Nov 2020 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '26 Nov 2020 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 89'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-11-29T00:02:09', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0a5a2837-5010-46f6-8758-6ade6d3c8c2e' User entered 'Yes (Y)'	System	29 Nov 2020 06:03:08
	System	29 Nov 2020 06:03:08

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

Have you been exposed to someone with 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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-11-29T00:02:20', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0a5a2837-5010-46f6-8758-6ade6d3c8c2e'	System	29 Nov 2020 06:03:08
User entered 'No (N)'	System	29 Nov 2020 06:03:08

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-11-29T00:02:26', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0a5a2837-5010-46f6-8758-6ade6d3c8c2e'	System	29 Nov 2020 06:03:08
User entered 'No (N)'	System	29 Nov 2020 06:03:08

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-11-29T00:02:33', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0a5a2837-5010-46f6-8758-6ade6d3c8c2e' User entered 'Yes (Y)'	System	29 Nov 2020 06:03:08
	System	29 Nov 2020 06:03:08

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Please 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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-11-29T00:02:46', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0a5a2837-5010-46f6-8758-6ade6d3c8c2e'	System	29 Nov 2020 06:03:08
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	29 Nov 2020 06:03:08



**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-11-29T00:02:53', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0a5a2837-5010-46f6-8758-6ade6d3c8c2e' User entered '29 Nov 2020 00:02:53'	System	29 Nov 2020 06:03:08
	System	29 Nov 2020 06:03:08

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '29 Nov 2020 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '03 Dec 2020 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-12-06T21:21:55', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '94027eeb-41c9-4234-9ce4-cbc44a504082' User entered 'No (N)'	System	07 Dec 2020 03:22:26
	System	07 Dec 2020 03:22:26

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

Have you been exposed to someone with 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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-12-06T21:22:00', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '94027eeb-41c9-4234-9ce4-cbc44a504082' User entered 'No (N)'	System	07 Dec 2020 03:22:26
	System	07 Dec 2020 03:22:26

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-12-06T21:22:14', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '94027eeb-41c9-4234-9ce4-cbc44a504082' User entered '06 Dec 2020 21:22:14'	System	07 Dec 2020 03:22:26
	System	07 Dec 2020 03:22:26

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '06 Dec 2020 00:01'	System	20 Nov 2020 04:13:38



**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '10 Dec 2020 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-12-14T08:39:25', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '341d9ec4-a670-4cab-9290-8288d937671a' User entered 'No (N)'	System	14 Dec 2020 14:39:43
	System	14 Dec 2020 14:39:43

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

Have you been exposed to someone with 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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-12-14T08:39:28', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '341d9ec4-a670-4cab-9290-8288d937671a' User entered 'No (N)'	System	14 Dec 2020 14:39:43
	System	14 Dec 2020 14:39:43

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-12-14T08:39:38', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '341d9ec4-a670-4cab-9290-8288d937671a' User entered '14 Dec 2020 08:39:38'	System	14 Dec 2020 14:39:43
	System	14 Dec 2020 14:39:43

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '13 Dec 2020 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '17 Dec 2020 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 04:13:38



**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-12-23T09:18:15', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '96ac2a5b-85c6-4b1a-99c8-67114a51968a' User entered 'No (N)'	System	23 Dec 2020 15:18:34
	System	23 Dec 2020 15:18:34

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

Have you been exposed to someone with 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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-12-23T09:18:23', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '96ac2a5b-85c6-4b1a-99c8-67114a51968a' User entered 'No (N)'	System	23 Dec 2020 15:18:34
	System	23 Dec 2020 15:18:34

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-12-23T09:18:31', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '96ac2a5b-85c6-4b1a-99c8-67114a51968a' User entered '23 Dec 2020 09:18:31'	System	23 Dec 2020 15:18:34
	System	23 Dec 2020 15:18:34

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '20 Dec 2020 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '24 Dec 2020 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-12-27T08:07:36', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '03b5011f-6301-44c8-8051-838c5e6ec7a5'	System	27 Dec 2020 14:08:00
User entered 'No (N)'	System	27 Dec 2020 14:08:00

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Have you been exposed to someone with 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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-12-27T08:07:43', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '03b5011f-6301-44c8-8051-838c5e6ec7a5' User entered 'No (N)'	System	27 Dec 2020 14:08:00
	System	27 Dec 2020 14:08:00



**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2020-12-27T08:07:56', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '03b5011f-6301-44c8-8051-838c5e6ec7a5' User entered '27 Dec 2020 08:07:56'	System	27 Dec 2020 14:08:00
	System	27 Dec 2020 14:08:00

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '27 Dec 2020 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '31 Dec 2020 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-01-03T00:22:15', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '5b285baf-fe76-4ada-aae8-c4d5b80681d0'	System	03 Jan 2021 06:22:35
User entered 'No (N)'	System	03 Jan 2021 06:22:35

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

Have you been exposed to someone with 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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-01-03T00:22:21', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '5b285baf-fe76-4ada-aae8-c4d5b80681d0'	System	03 Jan 2021 06:22:35
User entered 'No (N)'	System	03 Jan 2021 06:22:35

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-01-03T00:22:33', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '5b285baf-fe76-4ada-aae8-c4d5b80681d0' User entered '03 Jan 2021 00:22:33'	System	03 Jan 2021 06:22:35
	System	03 Jan 2021 06:22:35

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '03 Jan 2021 00:01'	System	20 Nov 2020 04:13:38



**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '07 Jan 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-01-11T10:49:59', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0a17115c-84b4-477a-8690-777d0374921c'	System	11 Jan 2021 16:50:16
User entered 'No (N)'	System	11 Jan 2021 16:50:16

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Have you been exposed to someone with 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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-01-11T10:50:03', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0a17115c-84b4-477a-8690-777d0374921c' User entered 'No (N)'	System	11 Jan 2021 16:50:16

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-01-11T10:50:14', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0a17115c-84b4-477a-8690-777d0374921c' User entered '11 Jan 2021 10:50:14'	System	11 Jan 2021 16:50:16
	System	11 Jan 2021 16:50:16

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '10 Jan 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '14 Jan 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 04:13:38



**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-01-18T16:02:26', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4cead797-ceda-45b1-82e3-18c4c6a943fe' User entered 'No (N)'	System	18 Jan 2021 22:05:11

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Have you been exposed to someone with 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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-01-18T16:02:32', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4cead797-ceda-45b1-82e3-18c4c6a943fe' User entered 'No (N)'	System	18 Jan 2021 22:05:11

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-01-18T16:05:03', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '4cead797-ceda-45b1-82e3-18c4c6a943fe' User entered '18 Jan 2021 16:05:03'	System	18 Jan 2021 22:05:11
	System	18 Jan 2021 22:05:11

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '17 Jan 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '21 Jan 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-01-24T15:46:37', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '51b1c7c9-2bb1-47db-8936-188e0eaa14b6' User entered 'No (N)'	System	24 Jan 2021 22:21:14
	System	24 Jan 2021 22:21:14

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

Have you been exposed to someone with 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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-01-24T15:46:43', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '51b1c7c9-2bb1-47db-8936-188e0eaa14b6' User entered 'No (N)'	System	24 Jan 2021 22:21:14



**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-01-24T15:46:53', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '51b1c7c9-2bb1-47db-8936-188e0eaa14b6' User entered '24 Jan 2021 15:46:53'	System	24 Jan 2021 22:21:14
	System	24 Jan 2021 22:21:14

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '24 Jan 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '28 Jan 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-02-02T09:39:27', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '08c06a31-ed0e-4f04-ac69-4b751cf9b090' User entered 'No (N)'	System	02 Feb 2021 15:40:07
	System	02 Feb 2021 15:40:07

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Have you been exposed to someone with 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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-02-02T09:39:33', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '08c06a31-ed0e-4f04-ac69-4b751cf9b090'	System	02 Feb 2021 15:40:07
User entered 'No (N)'	System	02 Feb 2021 15:40:07

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-02-02T09:40:00', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '08c06a31-ed0e-4f04-ac69-4b751cf9b090' User entered '02 Feb 2021 09:40:00'	System	02 Feb 2021 15:40:07
	System	02 Feb 2021 15:40:07

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '31 Jan 2021 00:01'	System	20 Nov 2020 04:13:38



**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '04 Feb 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-02-10T19:47:37', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'd909fef0-5b80-47a9-aecb-48e4e3029935'	System	11 Feb 2021 01:47:54
User entered 'No (N)'	System	11 Feb 2021 01:47:54

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Have you been exposed to someone with 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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-02-10T19:47:44', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'd909fef0-5b80-47a9-aecb-48e4e3029935'	System	11 Feb 2021 01:47:54
User entered 'No (N)'	System	11 Feb 2021 01:47:54

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-02-10T19:47:51', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'd909fef0-5b80-47a9-aecb-48e4e3029935' User entered '10 Feb 2021 19:47:51'	System	11 Feb 2021 01:47:54
	System	11 Feb 2021 01:47:54

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '07 Feb 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '11 Feb 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 04:13:38



**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-02-16T10:36:23', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '69db6c4c-266c-4b94-8a14-46e9f9437614' User entered 'No (N)'	System	16 Feb 2021 16:37:06
	System	16 Feb 2021 16:37:06

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

Have you been exposed to someone with 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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-02-16T10:36:59', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '69db6c4c-266c-4b94-8a14-46e9f9437614' User entered 'No (N)'	System	16 Feb 2021 16:37:06
	System	16 Feb 2021 16:37:06

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-02-16T10:37:04', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '69db6c4c-266c-4b94-8a14-46e9f9437614' User entered '16 Feb 2021 10:37:04'	System	16 Feb 2021 16:37:06
	System	16 Feb 2021 16:37:06

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '14 Feb 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '18 Feb 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

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

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-02-21T00:05:00', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8e6380d8-60b2-4c3f-bdf3-8a44931f4f8f' User entered 'No (N)'	System	21 Feb 2021 06:05:13
	System	21 Feb 2021 06:05:13

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

Have you been exposed to someone with 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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-02-21T00:05:04', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8e6380d8-60b2-4c3f-bdf3-8a44931f4f8f' User entered 'No (N)'	System	21 Feb 2021 06:05:13
	System	21 Feb 2021 06:05:13



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-02-21T00:05:10', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '8e6380d8-60b2-4c3f-bdf3-8a44931f4f8f' User entered '21 Feb 2021 00:05:10'	System	21 Feb 2021 06:05:13
	System	21 Feb 2021 06:05:13

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '21 Feb 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '25 Feb 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-02-28T00:01:49', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'c07c89b1-a0fb-4eb7-92e1-9a0f588ada08'	System	28 Feb 2021 06:02:28
User entered 'No (N)'	System	28 Feb 2021 06:02:28

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Have you been exposed to someone with 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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-02-28T00:01:54', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'c07c89b1-a0fb-4eb7-92e1-9a0f588ada08'	System	28 Feb 2021 06:02:28
User entered 'No (N)'	System	28 Feb 2021 06:02:28

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-02-28T00:02:01', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'c07c89b1-a0fb-4eb7-92e1-9a0f588ada08' User entered '28 Feb 2021 00:02:01'	System	28 Feb 2021 06:02:28
	System	28 Feb 2021 06:02:28

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '28 Feb 2021 00:01'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '04 Mar 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-03-07T20:17:15', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'e5b65de8-daac-4ae4-94df-392f709f9708'	System	08 Mar 2021 02:25:51
User entered 'No (N)'	System	08 Mar 2021 02:25:51

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

Have you been exposed to someone with 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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-03-07T20:17:20', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'e5b65de8-daac-4ae4-94df-392f709f9708'	System	08 Mar 2021 02:25:51
User entered 'No (N)'	System	08 Mar 2021 02:25:51

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-03-07T20:17:52', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'e5b65de8-daac-4ae4-94df-392f709f9708' User entered '07 Mar 2021 20:17:52'	System	08 Mar 2021 02:25:51

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '07 Mar 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '11 Mar 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-03-16T09:28:14', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '777838c2-f454-48d2-919c-d01bae6dcf98'	System	16 Mar 2021 14:28:33
User entered 'No (N)'	System	16 Mar 2021 14:28:33

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Have you been exposed to someone with 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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-03-16T09:28:18', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '777838c2-f454-48d2-919c-d01bae6dcf98'	System	16 Mar 2021 14:28:33
User entered 'No (N)'	System	16 Mar 2021 14:28:33

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-03-16T09:28:28', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '777838c2-f454-48d2-919c-d01bae6dcf98' User entered '16 Mar 2021 09:28:28'	System	16 Mar 2021 14:28:33
	System	16 Mar 2021 14:28:33

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '14 Mar 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '18 Mar 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-03-21T14:43:02', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '30cf8936-5f94-4068-a328-2fb121c33f53'	System	21 Mar 2021 19:43:22
User entered 'No (N)'	System	21 Mar 2021 19:43:22

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

Have you been exposed to someone with 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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-03-21T14:43:06', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '30cf8936-5f94-4068-a328-2fb121c33f53'	System	21 Mar 2021 19:43:22
User entered 'No (N)'	System	21 Mar 2021 19:43:22



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-03-21T14:43:16', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '30cf8936-5f94-4068-a328-2fb121c33f53'	System	21 Mar 2021 19:43:22
User entered '21 Mar 2021 14:43:16'	System	21 Mar 2021 19:43:22

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '21 Mar 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '25 Mar 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-03-30T09:56:15', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'd066d492-5087-4492-b658-54d2bbd6f243'	System	30 Mar 2021 14:56:33
User entered 'No (N)'	System	30 Mar 2021 14:56:33

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Have you been exposed to someone with 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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-03-30T09:56:19', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'd066d492-5087-4492-b658-54d2bbd6f243'	System	30 Mar 2021 14:56:33
User entered 'No (N)'	System	30 Mar 2021 14:56:33

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-03-30T09:56:28', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'd066d492-5087-4492-b658-54d2bbd6f243'	System	30 Mar 2021 14:56:33
User entered '30 Mar 2021 09:56:28'	System	30 Mar 2021 14:56:33

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '28 Mar 2021 00:01'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '01 Apr 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-04-04T01:09:12', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '58b8903d-12c4-4448-92c0-c9836d5753b0'	System	04 Apr 2021 06:09:29
User entered 'No (N)'	System	04 Apr 2021 06:09:29

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

Have you been exposed to someone with 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 (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-04-04T01:09:17', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '58b8903d-12c4-4448-92c0-c9836d5753b0'	System	04 Apr 2021 06:09:29
User entered 'No (N)'	System	04 Apr 2021 06:09:29

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-04-04T01:09:27', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '58b8903d-12c4-4448-92c0-c9836d5753b0'	System	04 Apr 2021 06:09:29
User entered '04 Apr 2021 01:09:27'	System	04 Apr 2021 06:09:29

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '04 Apr 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '08 Apr 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (18222E7A-49EE-4E0D-8E4B-184E79CB0942)', Time: '2021-04-14T10:16:32', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '18070ce0-6474-4cea-b23a-72e29d72261a' User entered 'No (N)'	System	14 Apr 2021 15:16:46
	System	14 Apr 2021 15:16:46

US3782153

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 10 Jun 2021 09:44:15

Have you been exposed to someone with 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 (18222E7A-49EE-4E0D-8E4B-184E79CB0942)', Time: '2021-04-14T10:16:37', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '18070ce0-6474-4cea-b23a-72e29d72261a' User entered 'No (N)'	System	14 Apr 2021 15:16:46

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18222E7A-49EE-4E0D-8E4B-184E79CB0942)', Time: '2021-04-14T10:16:44', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '18070ce0-6474-4cea-b23a-72e29d72261a' User entered '14 Apr 2021 10:16:44'	System	14 Apr 2021 15:16:46
	System	14 Apr 2021 15:16:46

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '11 Apr 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '15 Apr 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (18222E7A-49EE-4E0D-8E4B-184E79CB0942)', Time: '2021-04-18T00:06:30', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '15ecf122-73f6-4c9f-8ec8-ea22d2cf4e0b' User entered 'No (N)'	System	18 Apr 2021 05:06:42

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

Have you been exposed to someone with 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 (18222E7A-49EE-4E0D-8E4B-184E79CB0942)', Time: '2021-04-18T00:06:32', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '15ecf122-73f6-4c9f-8ec8-ea22d2cf4e0b' User entered 'No (N)'	System	18 Apr 2021 05:06:42



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18222E7A-49EE-4E0D-8E4B-184E79CB0942)', Time: '2021-04-18T00:06:39', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '15ecf122-73f6-4c9f-8ec8-ea22d2cf4e0b' User entered '18 Apr 2021 00:06:39'	System	18 Apr 2021 05:06:42
	System	18 Apr 2021 05:06:42

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '18 Apr 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '22 Apr 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (18222E7A-49EE-4E0D-8E4B-184E79CB0942)', Time: '2021-04-25T22:23:13', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0cd96a6d-22cf-4849-b868-9f7d3a9e2f42'	System	29 Apr 2021 13:57:29
User entered 'No (N)'	System	29 Apr 2021 13:57:29

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

Have you been exposed to someone with 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 (18222E7A-49EE-4E0D-8E4B-184E79CB0942)', Time: '2021-04-25T22:23:25', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0cd96a6d-22cf-4849-b868-9f7d3a9e2f42'	System	29 Apr 2021 13:57:29
User entered 'No (N)'	System	29 Apr 2021 13:57:29

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18222E7A-49EE-4E0D-8E4B-184E79CB0942)', Time: '2021-04-25T22:23:35', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: '0cd96a6d-22cf-4849-b868-9f7d3a9e2f42'	System	29 Apr 2021 13:57:29
User entered '25 Apr 2021 22:23:35'	System	29 Apr 2021 13:57:29

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '25 Apr 2021 00:01'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '29 Apr 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[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 (18222E7A-49EE-4E0D-8E4B-184E79CB0942)', Time: '2021-05-03T14:48:58', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'cb388c36-ebba-4b1c-9a86-3ef9933fccde' User entered 'No (N)'	System	03 May 2021 19:49:13
	System	03 May 2021 19:49:13

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Have you been exposed to someone with 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 (18222E7A-49EE-4E0D-8E4B-184E79CB0942)', Time: '2021-05-03T14:49:02', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'cb388c36-ebba-4b1c-9a86-3ef9933fccde' User entered 'No (N)'	System	03 May 2021 19:49:13

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (18222E7A-49EE-4E0D-8E4B-184E79CB0942)', Time: '2021-05-03T14:49:09', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'cb388c36-ebba-4b1c-9a86-3ef9933fccde' User entered '03 May 2021 14:49:09'	System	03 May 2021 19:49:13
	System	03 May 2021 19:49:13

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '02 May 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '06 May 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '09 May 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '13 May 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '16 May 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '20 May 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '23 May 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '27 May 2021 23:59'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '30 May 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '03 Jun 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '06 Jun 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '10 Jun 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '13 Jun 2021 00:01'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '17 Jun 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '20 Jun 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '24 Jun 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '27 Jun 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '01 Jul 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '04 Jul 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '08 Jul 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '11 Jul 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '15 Jul 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '18 Jul 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '22 Jul 2021 23:59'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '25 Jul 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '29 Jul 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '01 Aug 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '05 Aug 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '08 Aug 2021 00:01'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '12 Aug 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '15 Aug 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '19 Aug 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '22 Aug 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '26 Aug 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '29 Aug 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '02 Sep 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '05 Sep 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '09 Sep 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '12 Sep 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '16 Sep 2021 23:59'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '19 Sep 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '23 Sep 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '26 Sep 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '30 Sep 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '03 Oct 2021 00:01'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '07 Oct 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '10 Oct 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '14 Oct 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '17 Oct 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '21 Oct 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '24 Oct 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '28 Oct 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '31 Oct 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '04 Nov 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '07 Nov 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '11 Nov 2021 23:59'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '14 Nov 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '18 Nov 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '21 Nov 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '25 Nov 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '28 Nov 2021 00:01'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '02 Dec 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '05 Dec 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '09 Dec 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '12 Dec 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '16 Dec 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '19 Dec 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '23 Dec 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '26 Dec 2021 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '30 Dec 2021 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '02 Jan 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '06 Jan 2022 23:59'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '09 Jan 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '13 Jan 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '16 Jan 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '20 Jan 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '23 Jan 2022 00:01'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '27 Jan 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '30 Jan 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '03 Feb 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '06 Feb 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '10 Feb 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '13 Feb 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '17 Feb 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '20 Feb 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '24 Feb 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '27 Feb 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '03 Mar 2022 23:59'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '06 Mar 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '10 Mar 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '13 Mar 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '17 Mar 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '20 Mar 2022 00:01'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '24 Mar 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '27 Mar 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '31 Mar 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '03 Apr 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '07 Apr 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '10 Apr 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '14 Apr 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '17 Apr 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '21 Apr 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '24 Apr 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '28 Apr 2022 23:59'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '01 May 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '05 May 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '08 May 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '12 May 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '15 May 2022 00:01'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '19 May 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '22 May 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '26 May 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '29 May 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '02 Jun 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '05 Jun 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '09 Jun 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '12 Jun 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '16 Jun 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '19 Jun 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '23 Jun 2022 23:59'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '26 Jun 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '30 Jun 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '03 Jul 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '07 Jul 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '10 Jul 2022 00:01'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '14 Jul 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '17 Jul 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '21 Jul 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '24 Jul 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '28 Jul 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '31 Jul 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '04 Aug 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '07 Aug 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '11 Aug 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '14 Aug 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '18 Aug 2022 23:59'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '21 Aug 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '25 Aug 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '28 Aug 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '01 Sep 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '04 Sep 2022 00:01'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '08 Sep 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '11 Sep 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '15 Sep 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '18 Sep 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '22 Sep 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '25 Sep 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '29 Sep 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '02 Oct 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '06 Oct 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '09 Oct 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '13 Oct 2022 23:59'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '16 Oct 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '20 Oct 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '23 Oct 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '27 Oct 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '30 Oct 2022 00:01'	System	20 Nov 2020 04:13:38



**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '03 Nov 2022 23:59'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '06 Nov 2022 00:01'	System	20 Nov 2020 04:13:38

**US3782153**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 10 Jun 2021 09:44:15**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 04:13:38
Amendment Manager: User entered '10 Nov 2022 23:59'	System	20 Nov 2020 04:13:38

US3782153

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection\_ Dermal Filler eDiary (1)

Generated On: 10 Jun 2021 09:44:15

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-02-28T00:02:09', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'd4a86164-c529-4a2c-abbe-2fc8187c658b' User entered 'No (N)'	System	28 Feb 2021 06:02:49
	System	28 Feb 2021 06:02:49

**US3782153**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 14:17:13
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (1B2EA5C1-33BF-48A6-A4F0-E9927C06E511)', Time: '2021-02-28T00:02:14', User OID: 'PatientReportedOutcome (US3782153)', ODM File OID: 'd4a86164-c529-4a2c-abbe-2fc8187c658b' User entered '28 Feb 2021 00:02:14'	System	28 Feb 2021 06:02:49
	System	28 Feb 2021 06:02:49

US3782153

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	01 Dec 2020 19:14:59

US3782153

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '1 Dec 2020'	Carlton Griffin (b) (4)	01 Dec 2020 19:14:59



US3782153

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	01 Dec 2020 19:14:59

US3782153

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:14:59

US3782153

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	01 Dec 2020 19:15:14

**US3782153**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:44:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 15:24:16
User entered 'I'	System	01 Dec 2020 19:15:14

**US3782153**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:44:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:21
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	Trudy Sullivan (b) (4)	04 Jan 2021 19:17:19

**US3782153**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:44:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:21
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '4 Jan 2021'	Trudy Sullivan (b) (4)	04 Jan 2021 19:17:19

US3782153

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:21
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Trudy Sullivan (b) (4) (b) (4)	04 Jan 2021 19:17:19

**US3782153**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:44:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:21
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) Trudy Sullivan (b) (4)	04 Jan 2021 19:17:19



US3782153

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:21
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Trudy Sullivan (b) (4)	04 Jan 2021 19:17:39

**US3782153**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:44:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:21
User entered 'I'	System	04 Jan 2021 19:17:39

**US3782153**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:44:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:21
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:26
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	03 Feb 2021 16:04:49

US3782153

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:21
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:26
User entered '3 Feb 2021'	(b) (4) Carlton Griffin (b) (4) (b) (4)	03 Feb 2021 16:04:49

US3782153

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:21
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:26
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Carlton Griffin (b) (4)	03 Feb 2021 16:04:49

US3782153

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:21
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:26
User entered empty.	(b) (4) Carlton Griffin (b) (4)	03 Feb 2021 16:04:49

US3782153

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:21
User signature succeeded.	Spyros Kalams (b) (4)	19 Feb 2021 23:32:26
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	03 Feb 2021 16:04:55

**US3782153**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:44:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 10:21:21
User entered 'I'	System	03 Feb 2021 16:04:55



**US3782153**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:44:15**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:53:50
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:40:38

**US3782153**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:44:15**

**Date of Contact or Contact Attempt** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:53:50
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered '4 Mar 2021'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:40:38

US3782153

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 10 Jun 2021 09:44:15

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:53:50
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:40:38

**US3782153**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 10 Jun 2021 09:44:15**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:53:50
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:40:38

US3782153

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:53:50
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Mar 2021 16:40:46

**US3782153**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:44:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:53:50
User entered 'I'	System	04 Mar 2021 16:40:46

US3782153

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	06 Apr 2021 17:14:05

US3782153

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered '6 Apr 2021'	Carlton Griffin (b) (4)	06 Apr 2021 17:14:05



US3782153

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered 'Clinic (Clinic)'	Carlton Griffin (b) (4)	06 Apr 2021 17:14:05

**US3782153**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:44:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User entered 'VISIT4'	System	06 Apr 2021 17:14:05

US3782153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered 'No (N)'	Carlton Griffin (b) (4)	06 Apr 2021 17:14:16

US3782153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered empty.	Carlton Griffin (b) (4)	06 Apr 2021 17:14:16

US3782153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered empty.	Carlton Griffin (b) (4)	06 Apr 2021 17:14:16

**US3782153**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:44:15**

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User entered empty.	System	06 Apr 2021 17:14:16

US3782153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered empty.	Carlton Griffin (b) (4)	06 Apr 2021 17:14:16

US3782153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered empty.	Carlton Griffin (b) (4)	06 Apr 2021 17:14:16



US3782153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered empty.	Carlton Griffin (b) (4)	06 Apr 2021 17:14:16

US3782153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered empty.	Carlton Griffin (b) (4)	06 Apr 2021 17:14:16

**US3782153**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 10 Jun 2021 09:44:15**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User entered empty.	System	06 Apr 2021 17:14:16

US3782153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered empty.	Carlton Griffin (b) (4)	06 Apr 2021 17:14:16

US3782153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User entered empty.	System	06 Apr 2021 17:14:16

US3782153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered empty.	Carlton Griffin (b) (4)	06 Apr 2021 17:14:16

US3782153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User entered empty.	System	06 Apr 2021 17:14:16

US3782153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered empty.	Carlton Griffin (b) (4)	06 Apr 2021 17:14:16



US3782153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User entered empty.	System	06 Apr 2021 17:14:16

US3782153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01

US3782153

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 10 Jun 2021 09:44:15

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01

US3782153

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:44:15

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	06 Apr 2021 17:14:25

US3782153

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 10 Jun 2021 09:44:15

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered '6 Apr 2021'	Carlton Griffin (b) (4)	06 Apr 2021 17:14:25

US3782153

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	06 Apr 2021 17:14:52

US3782153

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered '6 Apr 2021'	(b) (4) Carlton Griffin (b) (4)	06 Apr 2021 17:14:52

US3782153

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:15

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered '12:15'	Carlton Griffin (b) (4)	06 Apr 2021 17:14:52



**US3782153**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:44:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User entered '6 Apr 2021 12:15'	System	06 Apr 2021 17:14:52

US3782153

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 10 Jun 2021 09:44:15

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	06 Apr 2021 17:14:32

**US3782153**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 10 Jun 2021 09:44:15**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 11:34:01
User entered 'I'	System	06 Apr 2021 17:14:32

US3782153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:15

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	14 Jan 2021 19:14:25

US3782153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:15

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '14 Jan 2021'	(b) (4) Carlton Griffin (b) (4) (b) (4)	14 Jan 2021 19:14:25

US3782153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 10 Jun 2021 09:44:15

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Clinic (Clinic)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	14 Jan 2021 19:14:25

**US3782153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Visit Date**

**Generated On: 10 Jun 2021 09:44:15**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User entered 'UNBLND_DECIDE'	System	14 Jan 2021 19:14:25

US3782153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:44:15

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '14 Jan 2021'	(b) (4) Carlton Griffin (b) (4) (b) (4)	14 Jan 2021 19:16:04



**US3782153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:44:15**

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:40:40

US3782153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:44:15

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	14 Jan 2021 19:16:04

**US3782153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:44:15**

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User signature succeeded.	Spyros Kalams (b) (4)	09 Apr 2021 01:20:49
User entered 'AMENDMENT 5 (AMENDMENT 5)'	(b) (4)	10 Mar 2021 16:55:28
WR# 5295537	System	
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 18:40:40

US3782153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:44:15

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User closed query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	(b) (4), (b) (6)	29 Jan 2021 07:38:00
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
Query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' answered with 'previously unblinded under protocol version amendment 5. received mRNA-1273 and will remain in the study ' (Site from System).	(b) (4) Carlton Griffin (b) (4)	14 Jan 2021 19:17:33
User opened query 'Date of unblinding is prior to the date of updated informed consent. Please reconcile.' (Site from System).	System	14 Jan 2021 19:16:04
User entered '22 Dec 2020'	Carlton Griffin (b) (4)	14 Jan 2021 19:16:04

US3782153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:44:15

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Carlton Griffin (b) (4)	14 Jan 2021 19:16:04

US3782153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:44:15

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 14:12:07
User entered 'mRNA-1273 (mRNA-1273)'	Carlton Griffin (b) (4) (b) (4)	14 Jan 2021 19:16:04

US3782153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:44:15

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) System	20 Jan 2021 14:12:07
User entered 'mRNA-1273 (mRNA-1273)'	Carlton Griffin (b) (4) (b) (4)	14 Jan 2021 19:16:04

US3782153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:44:15

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	14 Jan 2021 19:16:04



US3782153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 10 Jun 2021 09:44:15

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User entered empty.	System	14 Jan 2021 19:16:04

**US3782153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Unblinding**

**Generated On: 10 Jun 2021 09:44:15**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User entered empty.	System	14 Jan 2021 19:16:04

US3782153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4) (b) (4)	14 Jan 2021 19:19:11

US3782153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 10 Jun 2021 09:44:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '14 Jan 2021'	(b) (4) Carlton Griffin (b) (4) (b) (4)	14 Jan 2021 19:19:11

**US3782153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:44:15**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '13:18'	(b) (4) Carlton Griffin (b) (4) (b) (4)	14 Jan 2021 19:19:11

**US3782153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 10 Jun 2021 09:44:15**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User entered '14 Jan 2021 13:18'	System	14 Jan 2021 19:19:11

US3782153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:44:15

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) Carlton Griffin (b) (4)	14 Jan 2021 19:22:10

US3782153

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 10 Jun 2021 09:44:15

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '14 Jan 2021'	(b) (4) Carlton Griffin (b) (4) (b) (4)	14 Jan 2021 19:22:10



**US3782153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:44:15**

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '13:20'	(b) (4) Carlton Griffin (b) (4) (b) (4)	14 Jan 2021 19:22:10

**US3782153**

**Folder: Participant Decision Visit / OL-D1 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 10 Jun 2021 09:44:15**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 12:39:39
User entered '14 Jan 2021 13:20'	System	14 Jan 2021 19:22:10

US3782153

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 10 Jun 2021 09:44:15

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:09
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:16:15
User entered 'Yes (Y)'		29 Nov 2020 16:28:41

**US3782153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:44:15**

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:42:05
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:01
User entered	System	30 Nov 2020 16:38:54
'USA-US125-2020-mRNA-1273-P301000009'		
User entered 'New'	(b) (4), (b) (6)	30 Nov 2020 16:38:54

US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 20:42:05
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	Coder Import (b) (4)	29 Nov 2020 16:33:19
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Nov 2020 16:33:19
	(b) (4)	
Data point term sent to Coder	System	29 Nov 2020 16:31:51
User entered 'appendicitis'	(b) (4), (b) (6)	29 Nov 2020 16:31:14

US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Nov 2020 16:31:14

US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered 'No (N)'	(b) (4), (b) (6)	29 Nov 2020 16:31:14

US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered 'No (N)'	(b) (4), (b) (6)	29 Nov 2020 16:31:14



US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered '26 Nov 2020'	(b) (4), (b) (6)	29 Nov 2020 16:31:14

**US3782153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:31:14

**US3782153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:44:15**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Nov 2020 16:31:14

**US3782153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered 'No (N)'	(b) (4), (b) (6)	29 Nov 2020 16:31:14

US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered '27 Nov 2020'	(b) (4), (b) (6)	29 Nov 2020 16:31:14

**US3782153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:44:15**

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:31:14

**US3782153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:44:15**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Nov 2020 16:31:14

US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6)	29 Nov 2020 16:31:14



US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	29 Nov 2020 16:34:45
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	29 Nov 2020 16:34:45
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Nov 2020 16:34:45
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	29 Nov 2020 16:32:28
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	29 Nov 2020 16:32:28
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Nov 2020 16:32:28
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	29 Nov 2020 16:32:00
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	29 Nov 2020 16:32:00
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	29 Nov 2020 16:32:00
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Nov 2020 16:32:00
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	29 Nov 2020 16:31:14
User entered 'No (N)'	(b) (4), (b) (6)	29 Nov 2020 16:31:14

**US3782153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered '0'	(b) (4), (b) (6)	29 Nov 2020 16:31:14

US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered '0'	(b) (4), (b) (6)	29 Nov 2020 16:31:14

US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered '0'	(b) (4), (b) (6)	29 Nov 2020 16:31:14

US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:31:14

US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:31:14

**US3782153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:31:14

**US3782153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:31:14



**US3782153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered '0'	(b) (4), (b) (6)	29 Nov 2020 16:31:14

US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered '0'	(b) (4), (b) (6)	29 Nov 2020 16:31:14

US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User closed query 'PV Query: Was the subject hospitalized overnight for the event with surgery? If so please consider serious criterion of hospitalization and reassess medically significant.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 14:36:22
Query 'PV Query: Was the subject hospitalized overnight for the event with surgery? If so please consider serious criterion of hospitalization and reassess medically significant.' answered with 'subject was not hospitalized overnight for the event with surgery ' (Site from Safety).	Carlton Griffin (b) (4) (b) (4)	08 Dec 2020 14:51:42
User opened query 'PV Query: Was the subject hospitalized overnight for the event with surgery? If so please consider serious criterion of hospitalization and reassess medically significant.' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 18:36:00
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Nov 2020 16:34:45
User entered '0'	(b) (4), (b) (6)	29 Nov 2020 16:31:14

**US3782153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	29 Nov 2020 16:31:14

US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	29 Nov 2020 16:31:14

**US3782153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	29 Nov 2020 16:31:14

US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

None

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered '0'	(b) (4), (b) (6)	29 Nov 2020 16:31:14

US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered 'I'	(b) (4), (b) (6)	29 Nov 2020 16:31:14



US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered 'I'	(b) (4), (b) (6)	29 Nov 2020 16:31:14

US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	17 Dec 2020 18:32:34
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	17 Dec 2020 18:26:16
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4), (b) (6)	17 Dec 2020 18:26:16
User closed query 'PV Query: Please reassess if the outcome needs to be updated to "resolved." Is an appendectomy a pathological condition as 'Sequelae'?' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 14:36:32
Query 'PV Query: Please reassess if the outcome needs to be updated to "resolved." Is an appendectomy a pathological condition as 'Sequelae'?' answered with 'the sequela is the post op pain from the appendectomy. ' (Site from Safety).	Carlton Griffin (b) (4) (b) (4)	08 Dec 2020 14:53:24
User opened query 'PV Query: Please reassess if the outcome needs to be updated to "resolved." Is an appendectomy a pathological condition as 'Sequelae'?' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 18:41:32
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	29 Nov 2020 16:32:28
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Nov 2020 16:32:28
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	29 Nov 2020 16:31:14
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	29 Nov 2020 16:31:14

US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

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 20:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:42:05
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 18:32:34
User entered 'continues with post-op pain but actual adverse event resolved with surgical procedure'	(b) (4), (b) (6)	29 Nov 2020 16:31:14

US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:42:05
User closed query 'PV Query: Please provide the surgical report when available.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 14:36:59
User closed query 'PV query: Please provide results of any laboratory studies.' (Site from Safety).	(b) (4), (b) (6)	09 Dec 2020 14:36:51
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)	09 Dec 2020 14:36:41
Query 'PV Query: Please provide the surgical report when available.' answered with 'patient did not consent to release of her full medical records to study clinic.' (Site from Safety).	Carlton Griffin (b) (4) (b) (4)	08 Dec 2020 19:08:38
Query 'PV query: Please provide results of any laboratory studies.' answered with 'patient did not consent to release of her full medical records to study clinic.' (Site from Safety).	Carlton Griffin (b) (4) (b) (4)	08 Dec 2020 19:08:34
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 'patient did not consent to release any medical records with study clinic.' (Site from Safety).	Carlton Griffin (b) (4) (b) (4)	08 Dec 2020 19:08:10
Query 'PV Query: Was the subject hospitalized overnight for the event with surgery? If so please consider serious criterion of hospitalization and reassess medically significant.' canceled (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 18:44:37
User opened query 'PV Query: Please provide the surgical report when available.' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 18:42:18
User opened query 'PV query: Please provide results of any laboratory studies.' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 18:42:03
Query 'IQVIA medical query: Please provide results of any laboratory studies.' canceled (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 18:41:55

US3782153

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 10 Jun 2021 09:44:15

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'IQVIA medical query: Please provide results of any laboratory studies.' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 18:41:50
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 18:35:33
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.' canceled (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 18:35:23
User opened query 'PV Query: Was the subject hospitalized overnight for the event with surgery? If so please consider serious criterion of hospitalization and reassess medically significant.' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 18:34:49
User opened query 'Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	06 Dec 2020 18:34:34
User entered 'chief complaint rt. ABD pain on 26-NOV-2020, CT confirmed appendicitis, had appendectomy 27-NOV-2020'	(b) (4), (b) (6)	29 Nov 2020 16:31:14

**US3782153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Nov 2020 16:34:45
User entered '0'	System	29 Nov 2020 16:32:28
User entered '1'	System	29 Nov 2020 16:32:00
User entered '0'	System	29 Nov 2020 16:31:14

**US3782153**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Nov 2020 16:31:14

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 10 Jun 2021 09:44:15

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:09
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:58:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	04 Sep 2020 20:59:29



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Sep 2020 21:15:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 21:15:48
Data point term sent to Coder	System	04 Sep 2020 21:14:21
User entered 'amlodopine'	(b) (4), (b) (6)	04 Sep 2020 21:13:44

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:13:44

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:13:44

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '5'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:13:44

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:13:44

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:44:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:13:44

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:13:44

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:44:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:13:44



US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:13:44

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:44:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:13:44

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'un UNK 2012'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:13:44

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:13:44

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:13:44

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:44:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:13:44

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:13:44

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:13:44



US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:13:44

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 21:13:44

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Sep 2020 21:16:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 21:16:49
Data point term sent to Coder	System	04 Sep 2020 21:15:23
User entered 'losartan'	(b) (4), (b) (6)	04 Sep 2020 21:14:50

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:14:50

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:44:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:14:50

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:44:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '100'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:14:50

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:14:50

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:44:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:14:50



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:14:50

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:44:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:14:50

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:44:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:14:50

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:44:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:14:50

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 10 Jun 2021 09:44:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'un May 2012'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:14:50

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:14:50

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:44:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:14:50

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:44:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:14:50



US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:44:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:14:50

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:14:50

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:14:50

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 21:14:50

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL SUCCINATE, PRODUCTSYNONYM: TOPROL XL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	04 Sep 2020 21:17:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 21:17:51
Data point term sent to Coder	System	04 Sep 2020 21:16:25
User entered 'toprol XL'	(b) (4), (b) (6)	04 Sep 2020 21:16:18

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:16:18

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:44:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:16:18

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:44:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '100'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:16:18



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:16:18

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:44:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:16:18

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:16:18

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:44:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:16:18

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:44:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:16:18

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:44:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:16:18

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'un UNK 2006'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:16:18

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:16:18



**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:44:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:16:18

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:44:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:16:18

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:44:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:16:18

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:16:18

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:16:18

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 21:16:18

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: BABY ASPIRIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Sep 2020 21:18:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 21:18:52
Data point term sent to Coder	System	04 Sep 2020 21:18:27
User entered 'baby aspirin'	(b) (4), (b) (6)	04 Sep 2020 21:17:49

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:17:49



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'cardiovascular prophylaxis'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:17:49

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:44:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '81'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:17:49

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:17:49

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:44:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:17:49

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:17:49

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:44:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:17:49

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:44:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:17:49

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:44:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:17:49



US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'un Oct 2016'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:17:49

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:17:49

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:44:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:17:49

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:44:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:17:49

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:44:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:17:49

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:17:49

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:17:49

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 21:17:49



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: BUPROPION - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Sep 2020 21:22:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 21:22:42
Data point term sent to Coder	System	04 Sep 2020 21:21:32
User entered 'bupropion'	(b) (4), (b) (6)	04 Sep 2020 21:21:20

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:21:20

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:44:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'depression'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:21:20

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:44:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '450'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:21:20

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:21:20

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:44:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:21:20

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:21:20

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:44:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:21:20



**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:44:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:21:20

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:44:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:21:20

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'un UNK 2016'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:21:20

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:21:20

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:34:01
User entered 'No (N)'	(b) (4), (b) (6)	04 Sep 2020 21:21:20

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 10 Jun 2021 09:44:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User closed query 'Ongoing is No, however End date System is missing. Please provide.' (Site from System).		04 Sep 2020 21:34:01
User opened query 'Ongoing is No, however End dateSystem is missing. Please provide.' (Site from System).		04 Sep 2020 21:21:20
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 21:21:20

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:44:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:21:20

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:21:20



US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:21:20

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 21:21:20

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Nov 2020 13:53:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Nov 2020 13:53:18
Data point term sent to Coder	System	28 Oct 2020 14:02:28
Coding entries removed.	Carlton Griffin (b) (4) (b) (4)	28 Oct 2020 14:02:00
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: DEXAMETHASONE, PRODUCTSYNONYM: DECADRON [DEXAMETHASONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 05:27:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 05:27:43
Data point term sent to Coder	System	04 Sep 2020 21:31:55
User entered 'decadron'	(b) (4), (b) (6)	04 Sep 2020 21:31:47

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:31:47

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User closed query 'Per DM CLR: Please update the indication to reflect the location of CONTACT DERMATITIS. Please reconcile with the AE and Med History eCRFs as appropriate. (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Nov 2020 11:09:34
Query 'Per DM CLR: Please update the indication to reflect the location of CONTACT DERMATITIS. Please reconcile with the AE and Med History eCRFs as appropriate. answered with 'updated thanks' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	28 Oct 2020 14:03:58
User entered 'GENERALIZED CONTACT DERMATITIS' reason for change: Per Query Resolution	Carlton Griffin (b) (4) (b) (4)	28 Oct 2020 14:02:00
User opened query 'Per DM CLR: Please update the indication to reflect the location of CONTACT DERMATITIS. Please reconcile with the AE and Med History eCRFs as appropriate. (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 21:07:57
User entered 'contact dermatitis'	(b) (4), (b) (6)	04 Sep 2020 21:31:47

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:44:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '4'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:31:47

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:44:15**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:31:47

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:44:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:31:47



US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:44:15**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:31:47

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:44:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:31:47

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:44:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:31:47

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:44:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:31:47

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:31:47

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:31:47

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:44:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:31:47

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 10 Jun 2021 09:44:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	04 Sep 2020 21:34:35
User entered '24 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:34:35
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	04 Sep 2020 21:31:47
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 21:31:47



US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:44:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:31:47

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 21:31:47

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 21:31:47

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Sep 2020 21:31:47

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Nov 2020 03:53:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 03:53:51
Data point term sent to Coder	System	28 Oct 2020 14:04:29
Coding entries removed.	Carlton Griffin (b) (4) (b) (4)	28 Oct 2020 14:04:15
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: TRIAMCINOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 07:28:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 07:28:46
Data point term sent to Coder	System	04 Sep 2020 21:33:58
User entered 'triamcinolone'	(b) (4), (b) (6)	04 Sep 2020 21:33:33

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:33:33

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User closed query 'Per DM CLR: Please update the indication to reflect the location of CONTACT DERMATITIS. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:12:59
Query 'Per DM CLR: Please update the indication to reflect the location of CONTACT DERMATITIS. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'updated thanks' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	28 Oct 2020 14:04:21
User entered 'GENERALIZED CONTACT DERMATITIS' reason for change: Per Query Resolution	Carlton Griffin (b) (4) (b) (4)	28 Oct 2020 14:04:15
User opened query 'Per DM CLR: Please update the indication to reflect the location of CONTACT DERMATITIS. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 21:08:24
User entered 'contact dermatitis'	(b) (4), (b) (6)	04 Sep 2020 21:33:33

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:44:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '40'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:33:33



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:33:33

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:44:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:33:33

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:33:33

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:44:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:33:33

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:44:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:33:33

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:44:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:33:33

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:33:33

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:33:33



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:33:33

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 10 Jun 2021 09:44:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User closed query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	(b) (4)	04 Sep 2020 21:35:14
User entered '24 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:35:14
User opened query 'Ongoing is No, however End date is missing. Please provide.' (Site from System).	System	04 Sep 2020 21:33:33
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 21:33:33

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:44:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:33:33

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:33:33

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:33:33

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 21:33:33

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 Nov 2020 04:54:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Nov 2020 04:54:41
Data point term sent to Coder	System	28 Oct 2020 14:05:30
Coding entries removed.	Carlton Griffin (b) (4) (b) (4)	28 Oct 2020 14:04:38
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, ATC: CORTICOSTEROIDS FOR SYSTEMIC USE, PLAIN, ATC: GLUCOCORTICIDS, PRODUCT: PREDNISONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 07:15:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 07:15:44
Data point term sent to Coder	System	04 Sep 2020 21:38:07
User entered 'prednisone taper'	(b) (4), (b) (6)	04 Sep 2020 21:37:34

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:37:34



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User closed query 'Per DM CLR: Please update the indication to reflect the location of CONTACT DERMATITIS. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Nov 2020 15:13:25
Query 'Per DM CLR: Please update the indication to reflect the location of CONTACT DERMATITIS. Please reconcile with the AE and Med History eCRFs as appropriate. ' answered with 'UPDATED THANKS' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	28 Oct 2020 14:04:44
User entered 'GENERALIZED CONTACT DERMATITIS' reason for change: Per Query Resolution	Carlton Griffin (b) (4) (b) (4)	28 Oct 2020 14:04:38
User opened query 'Per DM CLR: Please update the indication to reflect the location of CONTACT DERMATITIS. Please reconcile with the AE and Med History eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Oct 2020 21:08:44
User entered 'contact dermatitis'	(b) (4), (b) (6)	04 Sep 2020 21:37:34

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:15

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the dose to record each tapering dose into separate logline. Update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 14:20:01
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
Query 'Per DM CLR: Please review the dose to record each tapering dose into separate logline. Update as appropriate, otherwise clarify.' answered with 'see frequency' (Site from DM).	Carlton Griffin (b) (4)	05 Jan 2021 13:39:03
User entered '60-20' reason for change: Data Entry Error	Carlton Griffin (b) (4)	05 Jan 2021 13:38:44
User entered '60, 50, 40, 30, 20, 20' reason for change: Data Entry Error	Carlton Griffin (b) (4)	05 Jan 2021 13:37:25
User opened query 'Per DM CLR: Please review the dose to record each tapering dose into separate logline. Update as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	05 Jan 2021 10:55:52
User entered '60-20'	(b) (4), (b) (6)	04 Sep 2020 21:37:34

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:37:34

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:44:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:37:34

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'other (OTHER)' reason for change:	Carlton Griffin (b) (4)	05 Jan 2021 13:38:44
Data Entry Error	(b) (4)	
User entered 'once daily (QD)'	(b) (4), (b) (6)	04 Sep 2020 21:37:34

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 10 Jun 2021 09:44:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered '60mg, 50mg, 40mg, 30mg, 20mg, 20mg tapered on consecutive days' reason for change: Data Entry Error	Carlton Griffin (b) (4)	05 Jan 2021 13:38:44
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 21:37:34

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:44:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:37:34

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:44:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:37:34



US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '24 Aug 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:37:34

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:37:34

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:44:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:37:34

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:44:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '29 Aug 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:37:34

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:44:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:37:34

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Jan 2021 13:38:44
User entered '1'	System	04 Sep 2020 21:37:34

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Jan 2021 13:38:44
User entered '1'	System	04 Sep 2020 21:37:34

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Jan 2021 13:38:44
User entered '804 (804)'	System	04 Sep 2020 21:37:34



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Sep 2020 05:23:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Sep 2020 05:23:47
Data point term sent to Coder	System	04 Sep 2020 21:40:08
User entered 'ceterizine'	(b) (4), (b) (6)	04 Sep 2020 21:39:47

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:39:47

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'allergic rhinitis'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:39:47

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:44:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '10'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:39:47

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:39:47

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:44:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:39:47

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:39:47

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:44:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:39:47



US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:44:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:39:47

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:44:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:39:47

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 10 Jun 2021 09:44:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'un UNK 2009'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:39:47

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:39:47

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:44:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:39:47

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:44:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:39:47

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:44:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:39:47

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:39:47



**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:39:47

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 21:39:47

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 21:43:41
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Sep 2020 21:43:41
	(b) (4)	
Data point term sent to Coder	System	04 Sep 2020 21:42:13
User entered 'lorazepam'	(b) (4), (b) (6)	04 Sep 2020 21:41:15

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:41:15

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:44:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'anxiety'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:41:15

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:44:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0.5'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:41:15

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:44:15**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:41:15

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:44:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:41:15



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:41:15

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:44:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:41:15

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:44:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:41:15

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:44:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:41:15

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'un Apr 2017'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:41:15

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:41:15

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:44:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:41:15

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:44:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:41:15



US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:44:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:41:15

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:41:15

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:41:15

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 21:41:15

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	04 Sep 2020 21:44:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 21:44:42
Data point term sent to Coder	System	04 Sep 2020 21:43:14
User entered 'omeprazole'	(b) (4), (b) (6)	04 Sep 2020 21:42:16

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:42:16

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 21:42:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Sep 2020 21:42:33
User entered 'GERD' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Sep 2020 21:42:33
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Sep 2020 21:42:16
User entered empty.	(b) (4), (b) (6)	04 Sep 2020 21:42:16

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:44:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '40'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:42:16



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:42:16

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:44:15**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:42:16

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:42:16

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:44:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:42:16

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:44:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:42:16

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:44:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:42:16

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'un UNK 2006'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:42:16

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:42:16



**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:44:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:42:16

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:44:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:42:16

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:44:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:42:16

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:42:16

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:42:16

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 21:42:16

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
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) (b) (4)	04 Sep 2020 21:45:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	04 Sep 2020 21:45:44
Data point term sent to Coder	System	04 Sep 2020 21:45:19
User entered 'rosuvastatin'	(b) (4), (b) (6)	04 Sep 2020 21:44:20

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:44:20



US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:44:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'hypercholesterolemia'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:44:20

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:44:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '5'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:44:20

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:44:15**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:44:20

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:44:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:44:20

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:44:20

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:44:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:44:20

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:44:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:44:20

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:44:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:44:20



US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'un Sep 2018'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:44:20

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:44:20

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 10 Jun 2021 09:44:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:44:20

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:44:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:44:20

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:44:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 21:44:20

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:44:20

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Sep 2020 21:44:20

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	04 Sep 2020 21:44:20



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: DRUGS FOR TREATMENT OF BONE DISEASES, ATC: DRUGS AFFECTING BONE STRUCTURE AND MINERALIZATION, ATC: BISPHOSPHONATES, PRODUCT: ZOLEDRONIC ACID, PRODUCTSYNONYM: RECLAST - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Sep 2020 18:14:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Sep 2020 18:14:35
Data point term sent to Coder	System	18 Sep 2020 18:13:41
User entered 'reclast'	Carlton Griffin (b) (4) (b) (4)	18 Sep 2020 18:13:28

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:44:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	18 Sep 2020 18:13:28
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'osteoporosis'	Carlton Griffin (b) (4)	18 Sep 2020 18:13:28
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:44:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered '5'	Carlton Griffin (b) (4)	18 Sep 2020 18:13:28
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'mg (mg)'	Carlton Griffin (b) (4)	18 Sep 2020 18:13:28
	(b) (4)	

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:44:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	18 Sep 2020 18:13:28
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'once (ONCE)'	Carlton Griffin (b) (4)	18 Sep 2020 18:13:28
	(b) (4)	

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:44:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	18 Sep 2020 18:13:28
	(b) (4)	



US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:44:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) Carlton Griffin (b) (4)	18 Sep 2020 18:13:28
	(b) (4)	

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:44:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	18 Sep 2020 18:13:28
	(b) (4)	

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered '18 Sep 2020'	Carlton Griffin (b) (4)	18 Sep 2020 18:13:28
	(b) (4)	

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	18 Sep 2020 18:13:28
	(b) (4)	

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:44:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	18 Sep 2020 18:13:28
	(b) (4)	

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:44:15**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered '18 Sep 2020'	Carlton Griffin (b) (4)	18 Sep 2020 18:13:28
	(b) (4)	

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:44:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'No (N)'	Carlton Griffin (b) (4)	18 Sep 2020 18:13:28
	(b) (4)	

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 18:13:28



US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 18:13:28

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Sep 2020 18:13:28

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:44:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	26 Sep 2020 05:54:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Sep 2020 05:54:40
Data point term sent to Coder	System	25 Sep 2020 19:50:28
Data point term sent to Coder	System	25 Sep 2020 19:49:27
User entered 'high dose influenza vaccination'	Carlton Griffin (b) (4) (b) (4)	25 Sep 2020 19:49:13

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:44:15**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'Yes (Y)'	Carlton Griffin (b) (4)	25 Sep 2020 19:49:13
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'influenza prophylaxis'	Carlton Griffin (b) (4)	25 Sep 2020 19:49:13
	(b) (4)	

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:44:15**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered '1'	Carlton Griffin (b) (4)	25 Sep 2020 19:49:13
	(b) (4)	

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:44:15**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'Other (OTHER)'	Carlton Griffin (b) (4)	25 Sep 2020 19:49:13
	(b) (4)	

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:44:15**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'injection'	Carlton Griffin (b) (4)	25 Sep 2020 19:49:13
	(b) (4)	



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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'once (ONCE)' reason for change: Data Entry Error	Carlton Griffin (b) (4)	25 Sep 2020 19:49:37
	(b) (4)	
User entered 'once daily (QD)'	Carlton Griffin (b) (4)	25 Sep 2020 19:49:13
	(b) (4)	

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:44:15**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	25 Sep 2020 19:49:13
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:44:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 19:49:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 19:49:37
User entered 'Intramuscular (INTRAMUSCULAR)' reason for change: Data Entry Error	Carlton Griffin (b) (4)	25 Sep 2020 19:49:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 19:49:13
User entered empty.	Carlton Griffin (b) (4)	25 Sep 2020 19:49:13
	(b) (4)	

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:44:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	25 Sep 2020 19:49:13
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:44:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	25 Sep 2020 19:49:37
User entered '21 Sep 2020' reason for change: Data Entry Error	Carlton Griffin (b) (4)	25 Sep 2020 19:49:37
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	25 Sep 2020 19:49:13
User entered empty.	Carlton Griffin (b) (4)	25 Sep 2020 19:49:13

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered '0'	Carlton Griffin (b) (4)	25 Sep 2020 19:49:13
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:44:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 19:49:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 19:49:37
User entered 'No (N)' reason for change: Data Entry Error	Carlton Griffin (b) (4)	25 Sep 2020 19:49:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 19:49:13
User entered empty.	Carlton Griffin (b) (4)	25 Sep 2020 19:49:13
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:44:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered '21 Sep 2020' reason for change: Data Entry Error	Carlton Griffin (b) (4)	25 Sep 2020 19:49:37
	(b) (4)	
User entered empty.	Carlton Griffin (b) (4)	25 Sep 2020 19:49:13
	(b) (4)	



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 10 Jun 2021 09:44:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 19:49:37
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Sep 2020 19:49:37
User entered 'No (N)' reason for change: Data Entry Error	Carlton Griffin (b) (4)	25 Sep 2020 19:49:37
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Sep 2020 19:49:13
User entered empty.	Carlton Griffin (b) (4)	25 Sep 2020 19:49:13
	(b) (4)	

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 19:49:37
User entered '1'	System	25 Sep 2020 19:49:13

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 19:49:37
User entered '1'	System	25 Sep 2020 19:49:13

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	25 Sep 2020 19:49:37
User entered '804 (804)'	System	25 Sep 2020 19:49:13

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:44:15

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 20:59:11
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: PROPOFOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 06:30:45
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 06:30:45
	(b) (4)	
Data point term sent to Coder	System	29 Nov 2020 16:46:54
User entered 'Propofol'	(b) (4), (b) (6)	29 Nov 2020 16:46:11

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:59:38
User entered 'No (N)'	(b) (4), (b) (6)	29 Nov 2020 16:46:11

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:59:42
User entered 'appendicitis'	(b) (4), (b) (6)	29 Nov 2020 16:46:11

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:44:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 20:59:48
User entered '100' reason for change: New Information	Carlton Griffin (b) (4)	01 Dec 2020 19:17:40
	(b) (4)	
User entered 'unk'	(b) (4), (b) (6)	29 Nov 2020 16:46:11



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	03 Feb 2021 18:54:15
Query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' answered with 'this is the correct unit for this dose' (Site from DM).	Carlton Griffin (b) (4) (b) (4)	02 Feb 2021 18:28:31
User opened query 'Per DM CLR: Please review the unit as this does not correspond to the given dose of this medication. Review and update as applicable. ' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 05:41:52
User signature succeeded.	Spyros Kalams (b) (4) (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 20:59:49
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Nov 2020 16:46:11

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:44:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:59:52
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:46:11

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:59:54
User entered 'once (ONCE)'	(b) (4), (b) (6)	29 Nov 2020 16:46:11

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:44:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:59:56
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:46:11

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:44:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:59:58
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	29 Nov 2020 16:46:11

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:44:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:00:00
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:46:11

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:44:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:02
User entered '27 Nov 2020'	(b) (4), (b) (6)	29 Nov 2020 16:46:11

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:44:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:04
User entered '0'	(b) (4), (b) (6)	29 Nov 2020 16:46:11



**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:44:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:06
User entered 'No (N)'	(b) (4), (b) (6)	29 Nov 2020 16:46:11

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:44:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:09
User entered '27 Nov 2020'	(b) (4), (b) (6)	29 Nov 2020 16:46:11

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 10 Jun 2021 09:44:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:11
User entered 'No (N)'	(b) (4), (b) (6)	29 Nov 2020 16:46:11

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Nov 2020 16:46:11

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Nov 2020 16:46:11

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (15)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Nov 2020 16:46:11

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:00:20
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 06:27:52
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 06:27:52
	(b) (4)	
Data point term sent to Coder	System	29 Nov 2020 16:46:52
User entered 'ceftriaxone'	(b) (4), (b) (6)	29 Nov 2020 16:46:51

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:22
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Nov 2020 16:46:51



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:23
User entered 'appendicitis'	(b) (4), (b) (6)	29 Nov 2020 16:46:51

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:44:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 15:17:12
User entered '2'	(b) (4), (b) (6)	29 Nov 2020 16:46:51

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:00:27
User entered 'g (g)'	(b) (4), (b) (6)	29 Nov 2020 16:46:51

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:44:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:29
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:46:51

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:32
User entered 'twice daily (BID)'	(b) (4), (b) (6)	29 Nov 2020 16:46:51

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:44:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:33
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:46:51

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:44:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:35
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	29 Nov 2020 16:46:51

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:44:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:37
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:46:51



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:44:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:39
User entered '27 Nov 2020'	(b) (4), (b) (6)	29 Nov 2020 16:46:51

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:44:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:40
User entered '0'	(b) (4), (b) (6)	29 Nov 2020 16:46:51

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:44:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:42
User entered 'No (N)'	(b) (4), (b) (6)	29 Nov 2020 16:46:51

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:44:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:00:43
User entered '27 Nov 2020'	(b) (4), (b) (6)	29 Nov 2020 16:46:51

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 10 Jun 2021 09:44:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:45
User entered 'No (N)'	(b) (4), (b) (6)	29 Nov 2020 16:46:51

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	29 Nov 2020 16:46:51

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	29 Nov 2020 16:46:51

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (16)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	29 Nov 2020 16:46:51



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:00:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 06:25:49
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 06:25:49
	(b) (4)	
Data point term sent to Coder	System	29 Nov 2020 16:47:54
User entered 'Morphine Sulfate'	(b) (4), (b) (6)	29 Nov 2020 16:47:27

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:52
User entered 'No (N)'	(b) (4), (b) (6)	29 Nov 2020 16:47:27

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:54
User entered 'appendicitis'	(b) (4), (b) (6)	29 Nov 2020 16:47:27

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:44:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:55
User entered 'I'	(b) (4), (b) (6)	29 Nov 2020 16:47:27

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:00:58
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Nov 2020 16:47:27

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:44:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:01
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:47:27

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:02
User entered 'once (ONCE)'	(b) (4), (b) (6)	29 Nov 2020 16:47:27

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:44:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:04
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:47:27



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:44:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:05
User entered 'Intravenous (INTRAVENOUS)'	(b) (4), (b) (6)	29 Nov 2020 16:47:27

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:44:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Jan 2021 21:01:07
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:47:27

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:44:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:09
User entered '27 Nov 2020'	(b) (4), (b) (6)	29 Nov 2020 16:47:27

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:44:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:10
User entered '0'	(b) (4), (b) (6)	29 Nov 2020 16:47:27

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:44:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:12
User entered 'No (N)'	(b) (4), (b) (6)	29 Nov 2020 16:47:27

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:44:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:14
User entered '27 Nov 2020'	(b) (4), (b) (6)	29 Nov 2020 16:47:27

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 10 Jun 2021 09:44:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:15
User entered 'No (N)'	(b) (4), (b) (6)	29 Nov 2020 16:47:27

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Nov 2020 16:47:27



US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Nov 2020 16:47:27

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (17)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Nov 2020 16:47:27

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Jan 2021 21:01:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 06:29:57
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 06:29:57
	(b) (4)	
Data point term sent to Coder	System	29 Nov 2020 16:48:56
User entered 'oxycodone'	(b) (4), (b) (6)	29 Nov 2020 16:47:56

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:30
User entered 'No (N)'	(b) (4), (b) (6)	29 Nov 2020 16:47:56

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:32
User entered 'appendicitis'	(b) (4), (b) (6)	29 Nov 2020 16:47:56

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:44:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:34
User entered '10'	(b) (4), (b) (6)	29 Nov 2020 16:47:56

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:35
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Nov 2020 16:47:56

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:44:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:37
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:47:56



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:39
User entered 'once (ONCE)'	(b) (4), (b) (6)	29 Nov 2020 16:47:56

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:44:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:42
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:47:56

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:44:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:44
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Nov 2020 16:47:56

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:44:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:46
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:47:56

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:44:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:48
User entered '27 Nov 2020'	(b) (4), (b) (6)	29 Nov 2020 16:47:56

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:44:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:50
User entered '0'	(b) (4), (b) (6)	29 Nov 2020 16:47:56

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:44:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:52
User entered 'No (N)'	(b) (4), (b) (6)	29 Nov 2020 16:47:56

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:44:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:54
User entered '27 Nov 2020'	(b) (4), (b) (6)	29 Nov 2020 16:47:56



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 10 Jun 2021 09:44:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 21:01:56
User entered 'No (N)'	(b) (4), (b) (6)	29 Nov 2020 16:47:56

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Nov 2020 16:47:56

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Nov 2020 16:47:56

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (18)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Nov 2020 16:47:56

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 15:18:40
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 06:29:57
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Nov 2020 06:29:57
	(b) (4)	
Data point term sent to Coder	System	29 Nov 2020 16:48:55
User entered 'oxycodone'	(b) (4), (b) (6)	29 Nov 2020 16:48:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:18:42
User entered 'No (N)'	(b) (4), (b) (6)	29 Nov 2020 16:48:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:18:44
User entered 'appendicitis (post-op pain)'	(b) (4), (b) (6)	29 Nov 2020 16:48:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:44:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:18:46
User entered '5'	(b) (4), (b) (6)	29 Nov 2020 16:48:30



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:18:48
User entered 'mg (mg)'	(b) (4), (b) (6)	29 Nov 2020 16:48:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:44:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:18:51
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:48:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:18:53
User entered 'as needed (PRN)'	(b) (4), (b) (6)	29 Nov 2020 16:48:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:44:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:18:54
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:48:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:44:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:18:57
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	29 Nov 2020 16:48:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:44:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:18:59
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:48:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:44:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:19:01
User entered '27 Nov 2020'	(b) (4), (b) (6)	29 Nov 2020 16:48:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:44:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:19:03
User entered '0'	(b) (4), (b) (6)	29 Nov 2020 16:48:30



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:44:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 15:19:06
User entered 'No (N)' reason for change: New Information	Carlton Griffin (b) (4)	01 Dec 2020 19:18:39
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Nov 2020 16:48:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:44:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:19:11
User entered '30 Nov 2020' reason for change: New Information	Carlton Griffin (b) (4)	01 Dec 2020 19:18:39
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 16:48:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 10 Jun 2021 09:44:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:19:18
User entered 'No (N)'	(b) (4), (b) (6)	29 Nov 2020 16:48:30

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Nov 2020 16:48:30

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Nov 2020 16:48:30

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (19)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Nov 2020 16:48:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 15:19:37
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.	Coder Import (b) (4)	01 Dec 2020 19:20:51
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Dec 2020 19:20:51
	(b) (4)	
Data point term sent to Coder	System	01 Dec 2020 19:20:08
User entered 'Tylenol'	Carlton Griffin (b) (4)	01 Dec 2020 19:19:12
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:19:38
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:19:12



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:19:40
User entered 'appendicitis (post-op pain)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:19:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:44:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:19:45
User entered '1000'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:19:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:19:47
User entered 'mg (mg)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:19:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:44:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:19:49
User entered empty.	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:19:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:19:51
User entered 'as needed (PRN)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:19:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:44:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:19:52
User entered empty.	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:19:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:44:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:19:53
User entered 'Oral (ORAL)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:19:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:44:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:19:55
User entered empty.	Carlton Griffin (b) (4)	01 Dec 2020 19:19:12
	(b) (4)	



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:44:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:19:57
User entered '30 Nov 2020'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:19:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:44:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:19:59
User entered '0'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:19:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:44:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:20:00
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	17 Dec 2020 18:25:35
User entered 'Yes (Y)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:19:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:44:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:20:04
User entered '14 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	17 Dec 2020 18:25:35
User entered empty.	Carlton Griffin (b) (4)	01 Dec 2020 19:19:12
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 10 Jun 2021 09:44:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:20:06
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:19:12

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:19:12

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:19:12

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (20)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:19:12



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:20:13
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)	02 Dec 2020 08:10:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Dec 2020 08:10:57
Data point term sent to Coder	System	01 Dec 2020 19:21:10
User entered 'zofran'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:20:25

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:20:14
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:20:25

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:20:16
User entered 'appendicitis'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:20:25

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:44:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:20:18
User entered '4'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:20:25

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:20:20
User entered 'mg (mg)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:20:25

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:44:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:20:24
User entered empty.	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:20:25

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:20:26
User entered 'once (ONCE)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:20:25

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:44:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:20:29
User entered empty.	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:20:25



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:44:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:20:32
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:20:25

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:44:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:20:35
User entered empty.	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:20:25

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:44:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:20:38
User entered '27 Nov 2020'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:20:25

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:21:37
User entered '0'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:20:25

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:44:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:21:39
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:20:25

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:44:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:28:44
User entered '27 Nov 2020'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:20:25

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 10 Jun 2021 09:44:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:31:00
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:20:25

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:20:25



US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:20:25

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (21)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:20:25

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:31:15
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: PHENYLEPHRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 20:49:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Dec 2020 20:49:45
Data point term sent to Coder	System	01 Dec 2020 19:23:15
User entered 'phenylephrine'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:22:32

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:31:20
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:22:32

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:32:40
User entered 'appendicitis'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:22:32

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:44:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 15:32:42
User entered '100'	Carlton Griffin (b) (4)	01 Dec 2020 19:22:32
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:32:44
User entered 'ug (ug)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:22:32

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:44:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:32:46
User entered empty.	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:22:32



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:32:49
User entered 'once (ONCE)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:22:32

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:44:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:32:52
User entered empty.	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:22:32

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:44:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:32:54
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:22:32

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:44:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:32:58
User entered empty.	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:22:32

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:44:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:00
User entered '27 Nov 2020'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:22:32

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:44:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:01
User entered '0'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:22:32

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:44:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:03
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:22:32

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:44:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:04
User entered '27 Nov 2020'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:22:32



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 10 Jun 2021 09:44:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:05
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:22:32

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:22:32

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:22:32

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (22)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:22:32

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 15:33:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 09:26:50
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 09:26:50
	(b) (4)	
Data point term sent to Coder	System	01 Dec 2020 19:24:17
User entered 'fentanyl'	Carlton Griffin (b) (4)	01 Dec 2020 19:23:30
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:24
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:23:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:26
User entered 'appendicitis '	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:23:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:44:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:28
User entered '75'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:23:30



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:31
User entered 'ug (ug)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:23:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:44:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:33
User entered empty.	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:23:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:35
User entered 'once (ONCE)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:23:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:44:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:37
User entered empty.	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:23:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:44:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:38
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:23:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:44:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:40
User entered empty.	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:23:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:44:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:43
User entered '27 Nov 2020'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:23:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:44:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:45
User entered '0'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:23:30



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:44:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:46
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:23:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:44:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:49
User entered '27 Nov 2020'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:23:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 10 Jun 2021 09:44:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:33:51
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:23:30

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:23:30

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:23:30

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (23)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:23:30

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 15:34:02
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 10:34:53
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Dec 2020 10:34:53
	(b) (4)	
Data point term sent to Coder	System	01 Dec 2020 19:25:18
User entered 'lidocaine'	Carlton Griffin (b) (4)	01 Dec 2020 19:24:19
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:34:04
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:24:19



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:34:05
User entered 'appendicitis'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:24:19

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:44:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:34:08
User entered '80'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:24:19

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:34:11
User entered 'mg (mg)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:24:19

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:44:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:34:14
User entered empty.	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:24:19

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:35:39
User entered 'once (ONCE)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:24:19

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:44:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:35:42
User entered empty.	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:24:19

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:44:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:35:44
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:24:19

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:44:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:35:48
User entered empty.	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:24:19



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:44:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:35:50
User entered '27 Nov 2020'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:24:19

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:44:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:35:53
User entered '0'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:24:19

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:44:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:35:56
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:24:19

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:44:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:35:58
User entered '27 Nov 2020'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:24:19

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 10 Jun 2021 09:44:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:35:59
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:24:19

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:24:19

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:24:19

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (24)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:24:19



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:36:11
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, PERIPHERALLY ACTING AGENTS, ATC: OTHER QUATERNARY AMMONIUM COMPOUNDS, PRODUCT: ROCURONIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Dec 2020 10:36:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Dec 2020 10:36:26
Data point term sent to Coder	System	01 Dec 2020 19:26:21
User entered 'rocuronium'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:26:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:36:12
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:26:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:36:14
User entered 'appendicitis'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:26:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:44:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:36:17
User entered '70'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:26:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:36:19
User entered 'mg (mg)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:26:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:44:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:36:22
User entered empty.	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:26:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:36:25
User entered 'once (ONCE)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:26:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:44:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:36:28
User entered empty.	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:26:12



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:44:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:36:30
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:26:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:44:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:36:32
User entered empty.	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:26:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:44:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:36:34
User entered '27 Nov 2020'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:26:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:44:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:41:40
User entered '0'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:26:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:44:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:41:44
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:26:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:44:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:41:47
User entered '27 Nov 2020'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:26:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 10 Jun 2021 09:44:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:41:51
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:26:12

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:26:12



US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:26:12

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (25)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:26:12

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 15:42:24
User coded data point as ATC: VARIOUS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ALL OTHER THERAPEUTIC PRODUCTS, ATC: ANTIDOTES, PRODUCT: SUGAMMADEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 12:50:16
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 12:50:16
	(b) (4)	
Data point term sent to Coder	System	01 Dec 2020 19:28:22
User entered 'sugammadex'	Carlton Griffin (b) (4)	01 Dec 2020 19:27:50
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:42:27
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:27:50

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:51:17
User entered 'appendicitis'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:27:50

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:44:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 15:51:19
User entered '200'	Carlton Griffin (b) (4)	01 Dec 2020 19:27:50
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:51:30
User entered 'mg (mg)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:27:50

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:44:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:51:34
User entered empty.	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:27:50



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:51:36
User entered 'once (ONCE)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:27:50

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:44:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:51:37
User entered empty.	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:27:50

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:44:15

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:51:39
User entered 'Intravenous (INTRAVENOUS)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:27:50

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:44:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:51:40
User entered empty.	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:27:50

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:44:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:51:42
User entered '27 Nov 2020'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:27:50

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:44:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 15:51:43
User entered '0'	Carlton Griffin (b) (4)	01 Dec 2020 19:27:50
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:44:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:51:45
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:27:50

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:44:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Jan 2021 15:51:48
User entered '27 Nov 2020'	Carlton Griffin (b) (4)	01 Dec 2020 19:27:50
	(b) (4)	



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 10 Jun 2021 09:44:15

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:51:50
User entered 'No (N)'	Carlton Griffin (b) (4) (b) (4)	01 Dec 2020 19:27:50

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:27:50

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:27:50

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (26)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	01 Dec 2020 19:27:50

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PNEUMOCOCCAL VACCINES, PRODUCT: PNEUMOCOCCAL VACCINE CONJ 7V (CRM197), PRODUCTSYNONYM: PREVNAR - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Jan 2021 15:45:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 15:45:44
Data point term sent to Coder	System	04 Jan 2021 21:11:08
User entered 'Pevnar23'	Trudy Sullivan (b) (4) (b) (4)	04 Jan 2021 21:10:34

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'Yes (Y)'	Trudy Sullivan (b) (4)	04 Jan 2021 21:10:34
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'Pneumococcal Prophylaxis'	Trudy Sullivan (b) (4)	04 Jan 2021 21:10:34
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:44:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered '0.5'	Trudy Sullivan (b) (4)	04 Jan 2021 21:10:34
	(b) (4)	



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:44:15

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'mL (mL)'	Trudy Sullivan (b) (4)	04 Jan 2021 21:10:34
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:44:15

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered empty.	Trudy Sullivan (b) (4)	04 Jan 2021 21:10:34
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'once (ONCE)'	Trudy Sullivan (b) (4)	04 Jan 2021 21:10:34
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:44:15

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered empty.	Trudy Sullivan (b) (4)	04 Jan 2021 21:10:34
	(b) (4)	

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:44:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Trudy Sullivan (b) (4)	04 Jan 2021 21:10:34
	(b) (4)	

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:44:15**

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered empty.	Trudy Sullivan (b) (4)	04 Jan 2021 21:10:34
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:44:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered '4 Jan 2021'	Trudy Sullivan (b) (4)	04 Jan 2021 21:10:34
	(b) (4)	

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:44:15**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered '0'	Trudy Sullivan (b) (4)	04 Jan 2021 21:10:34
	(b) (4)	



**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:44:15**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'No (N)'	Trudy Sullivan (b) (4)	04 Jan 2021 21:10:34
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 10 Jun 2021 09:44:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered '4 Jan 2021'	Trudy Sullivan (b) (4)	04 Jan 2021 21:10:34
	(b) (4)	

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:44:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'No (N)'	Trudy Sullivan (b) (4)	04 Jan 2021 21:10:34
	(b) (4)	

**US3782153**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 21:10:34

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 21:10:34

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (27)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 21:10:34

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:44:15

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID, PRODUCTSYNONYM: TDAP - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	05 Jan 2021 15:29:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	05 Jan 2021 15:29:44
Data point term sent to Coder	System	04 Jan 2021 21:14:10
User entered 'TDAP Vaccine'	Trudy Sullivan (b) (4) (b) (4)	04 Jan 2021 21:13:29

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:44:15

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'Yes (Y)'	Trudy Sullivan (b) (4)	04 Jan 2021 21:13:29
	(b) (4)	



US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:44:15**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Diphtheria, Tetanus, Pertussis Prophylaxis'	(b) (4) Trudy Sullivan (b) (4)	04 Jan 2021 21:13:29

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:44:15

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered '0.5'	Trudy Sullivan (b) (4)	04 Jan 2021 21:13:29
	(b) (4)	

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:44:15**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'mL (mL)'	Trudy Sullivan (b) (4)	04 Jan 2021 21:13:29
	(b) (4)	

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:44:15**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered empty.	Trudy Sullivan (b) (4)	04 Jan 2021 21:13:29
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:44:15

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'once (ONCE)'	Trudy Sullivan (b) (4)	04 Jan 2021 21:13:29
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:44:15

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered empty.	Trudy Sullivan (b) (4)	04 Jan 2021 21:13:29
	(b) (4)	

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:44:15**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Trudy Sullivan (b) (4)	04 Jan 2021 21:13:29
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:44:15

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered empty.	Trudy Sullivan (b) (4)	04 Jan 2021 21:13:29
	(b) (4)	



US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:44:15

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered '4 Jan 2021'	Trudy Sullivan (b) (4)	04 Jan 2021 21:13:29
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:44:15

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered '0'	Trudy Sullivan (b) (4)	04 Jan 2021 21:13:29
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:44:15

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'No (N)'	Trudy Sullivan (b) (4)	04 Jan 2021 21:13:29
	(b) (4)	

US3782153

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 10 Jun 2021 09:44:15

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered '4 Jan 2021'	Trudy Sullivan (b) (4)	04 Jan 2021 21:13:29
	(b) (4)	

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:44:15**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered 'No (N)'	Trudy Sullivan (b) (4)	04 Jan 2021 21:13:29
	(b) (4)	

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:44:15**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 21:13:29

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 21:13:29

US3782153

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (28)**

**Generated On: 10 Jun 2021 09:44:15**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Jan 2021 21:13:29



US3782153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 10 Jun 2021 09:44:15

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:51:09
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:58:43
User entered 'Yes (Y)'		29 Nov 2020 15:52:27

US3782153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:44:15

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:58:32
User entered '27 Nov 2020'	(b) (4), (b) (6)	29 Nov 2020 15:52:45

US3782153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:44:15

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:58:32
User entered 'appendectomy'	(b) (4), (b) (6)	29 Nov 2020 15:52:45

US3782153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:44:15

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:58:32
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	29 Nov 2020 15:52:45

US3782153

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 10 Jun 2021 09:44:15

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Jan 2021 20:58:32
User entered empty.	(b) (4), (b) (6)	29 Nov 2020 15:52:45

**US3782153**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:44:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'USA-US125-2020-MRNA-1273-P301000009'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

Serious

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'Yes (Y)'	System	30 Nov 2020 16:38:54

**US3782153**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:44:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'No (N)'	System	30 Nov 2020 16:38:54



US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'No (N)'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'No (N)'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'No (N)'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'No (N)'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'Yes (Y)'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'Spyros'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'Kalams'	System	30 Nov 2020 16:38:54

**US3782153**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:44:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered '1161 21st Avenue South'	System	30 Nov 2020 16:38:54



US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'Nashville'	System	30 Nov 2020 16:38:54

**US3782153**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:44:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered '37232'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 14:03:34
User entered 'US'	System	30 Nov 2020 16:39:20

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '2'	(b) (4)	18 Dec 2020 14:03:46
User entered '1'	System	30 Nov 2020 16:39:20

**US3782153**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:44:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered	System	30 Nov 2020 16:38:54
'USA-US125-2020-MRNA-1273-P301000009'		

**US3782153**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:44:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'Yes (Y)'	System	30 Nov 2020 16:38:54

**US3782153**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:44:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'No (N)'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'No (N)'	System	30 Nov 2020 16:38:54



US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'No (N)'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'No (N)'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'No (N)'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'Yes (Y)'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'Spyros'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'Kalams'	System	30 Nov 2020 16:38:54

**US3782153**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:44:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered '1161 21st Avenue South'	System	30 Nov 2020 16:38:54

**US3782153**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:44:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'Nashville'	System	30 Nov 2020 16:38:54



**US3782153**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:44:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered '37232'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 14:03:34
User entered 'US'	System	30 Nov 2020 16:39:20

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
User entered '2'	(b) (4)	18 Dec 2020 14:03:46
User entered '1'	System	30 Nov 2020 16:39:20

**US3782153**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000009**

**Form: Safety Report Form (1)**

**Generated On: 10 Jun 2021 09:44:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
User entered '30/Nov/2020 16:39'	System	30 Nov 2020 16:39:20

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 10 Jun 2021 09:44:15

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 14:03:34
User entered 'I'	(b) (4), (b) (6)	30 Nov 2020 16:39:20

**US3782153**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:44:15**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered	System	30 Nov 2020 16:38:54
'USA-US125-2020-MRNA-1273-P301000009'		

**US3782153**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:44:15**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'Yes (Y)'	System	30 Nov 2020 16:38:54

**US3782153**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:44:15**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'No (N)'	System	30 Nov 2020 16:38:54



US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'No (N)'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'No (N)'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'No (N)'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'No (N)'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'Yes (Y)'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'Spyros'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'Kalams'	System	30 Nov 2020 16:38:54

**US3782153**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:44:15**

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered '1161 21st Avenue South'	System	30 Nov 2020 16:38:54



**US3782153**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:44:15**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered 'Nashville'	System	30 Nov 2020 16:38:54

**US3782153**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000009**

**Form: Safety Report Form**

**Generated On: 10 Jun 2021 09:44:15**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 16:39:14
User entered '37232'	System	30 Nov 2020 16:38:54

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
Reviewed for Safety.	(b) (4), (b) (6)	18 Dec 2020 14:03:34
User entered 'US'	System	30 Nov 2020 16:39:20

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 10 Jun 2021 09:44:15

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
	(b) (4)	
User entered '2'	System	18 Dec 2020 14:03:46
User entered '1'	System	30 Nov 2020 16:39:20

**US3782153**

**Folder: SAE USA-US125-2020-MRNA-1273-P301000009**

**Form: Safety Report Form (2)**

**Generated On: 10 Jun 2021 09:44:15**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
User entered '18/Dec/2020 09:03'	System	18 Dec 2020 14:03:46

US3782153

Folder: SAE USA-US125-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 10 Jun 2021 09:44:15

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
User signature succeeded.	Spyros Kalams (b) (4)	26 Jan 2021 20:26:03
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 15:15:55
User entered 'I'	(b) (4), (b) (6)	18 Dec 2020 14:03:46